



110000472541

A1/A2/CO

NM541

RECEIVE

JAN 30 2009

Air/Toxics & Inspection
Coordination Branch
6EN-A

January 28, 2009

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics Santa Teresa, NM Plant
January 01, 2008 to June 30, 2008

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedance for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours, which is less than 5 percent of the total operating time for the reporting period. This facility is not required to have any Continuous Monitoring systems (CMS).

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide

- (C) Reporting Period Dates
Beginning: July 01, 2008
Ending: December 31, 2008

- (D) Description of Process Units
The facility process units are sterilization process chambers of various sizes using ethylene oxide gas as the sterilant. High concentration ethylene oxide process emissions are vented to an acid-water scrubber and low concentration ethylene oxide emissions are exhausted to a catalytic oxidizer abator.

- (E) Emission and Operating Parameter Limitations Specified in Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Abator	Catalytic bed temperature	Continuously monitor; >240°F
Scrubber	Scrubber tank liquid level	Record weekly

- (F) Monitoring Equipment Manufacturers and Model Numbers

Monitoring Equipment	Model Number	Serial Number
Honeywell Chart Recorder	Truline DR450T	8939760945047

- (G) Date of Latest CMS Certification or Audit
07-07-08 (Semi-Annual Calibration)

- (H) Total Operating Time of Affected Source during Reporting Period
Continuous, for a total of 4416 hours.

- (I) Emission Data Summary

Control Unit	Total Duration of Excess Emissions	Excess Emission Duration as % of Total Hours	Excess Emission Duration by Cause				
			Startup/Shutdown	Control Equipment Problems	Process Problems	Other Known Causes	Other Unknown Causes
Abator	0 hr	0%	0	0 hrs ¹	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

- (J) CMS Performance Summary

CMS Unit	Total CMS	Total CMS	CMS Downtime by Cause (hours)
----------	-----------	-----------	-------------------------------

	<u>Downtime</u>	<u>Downtime as % of Total Hours</u>	<u>Monitoring Equipment Malfunctions</u>	<u>Nonmonitorin g Equipment Malfunctions</u>	<u>Quality Control Calibratio ns</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Honeywell Chart Recorder	0 hr	0%	0	0	0	0	0

¹ July 17, 2008 -The Santa Theresa Facility experienced two power outages due to severe thunderstorms in the area. This severe weather caused two interruptions in the Donaldson Abator System. The interruptions cause the temperature of the Donaldson Abator to drop below 240°F for a total duration of 3 hours and 90 minutes. The Donaldson Abator System is equipped with an interlock system that prevents discharges to the atmosphere in the event the Donaldson Abator experiences control parameter malfunctions. The CMS is connected to a UPS backup battery supply therefore no downtime of the system occurred during the power outages. No emissions resulted from this breakdown.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
None.

(L) Responsible Official Certification
Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

KATH HOFFMAN

Kathleen Hoffman
Vice President – RA/QA

(M) Date of Report
January 29, 2008

If you have any questions regarding this report, please call Kathleen Hoffman at (630) 928-1758 or KHoffman@Sterigenics.com.

Sincerely,

KATH HOFFMAN

Kathleen Hoffman
Vice President – RA/QA

Cc: Ms. Mary Uhl
Program Manager, Compliance and Enforcement Section
State of New Mexico, Environment Department
Air Quality Bureau
PO Box 26110
Santa Fe, NM 87502-0110



AI/AI/CO 110000472541
NS41
V2

January 29, 2007

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics Santa Teresa, NM Plant
July 1, 2006 to December 31, 2006

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours which is less than 5 percent of the total operating time for the reporting period.

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide



11 0000472541
A1/A1/W

1541
v2
123

January 31, 2006

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RECEIVE

FEB 7 2006

Air/Toxics & Inspection
Coordination Branch
6EN-A

**RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics Santa Teresa, NM Plant**

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours which is less than 5 percent of the total operating time for the reporting period.

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: July 1, 2005
Ending: December 31, 2005

(D) Description of Process Units

The facility process units are sterilization process chambers of various sizes using ethylene oxide gas as the sterilant. High concentration ethylene oxide process emissions are vented to an acid-water scrubber and low concentration ethylene oxide emissions are exhausted to a catalytic oxidizer abator.

(E) Emission and Operating Parameter Limitations Specified in Relevant Standards

<u>Control Unit</u>	<u>Control Parameter</u>	<u>Limitations/Standards</u>
Abator	Catalytic bed temperature	Continuously monitor; must be greater than 240°F
Scrubber	Scrubber tank liquid level	Record weekly
Scrubber	Scrubber glycol solution pH	Record weekly; must be less than 2

(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart Recorder	Truline DR450T	N/A

(G) Date of Latest CMS Certification or Audit
6/30/05 (Semi-Annual Calibration)

(H) Total Operating Time of Affected Source during Reporting Period
Continuous.

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

<u>CMS Unit</u>	<u>Total CMS Downtime</u>	<u>Total CMS Downtime as % of Total Hours</u>	<u>CMS Downtime by Cause</u>				
			<u>Monitoring Equipment Malfunc-tions</u>	<u>Nonmoni-toring Equipment Malfunc-tions</u>	<u>Quality Control Calibra-tions</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Honeywell Chart Recorder	0 hr	0%	0	0	0	0	0

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
None.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

Kathleen Hoffman/RL
Kathleen Hoffman
Vice President – RA/QA

(M) Date of Report
January 31, 2006

If you have any questions regarding this report, please call Rosey Liu at (323) 586-9060.

Sincerely,

Kathleen Hoffman/RL
Kathleen Hoffman
Vice President – RA/QA



AL/H/LO

11 0000472541

NS41
v4

July 17, 2008

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RECEIVE

JUL 21 2008

Air/Toxics & Inspection
Coordination Branch
6EN-A

RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics Santa Teresa, NM Plant
January 01, 2008 to June 30, 2008

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours, which is less than 5 percent of the total operating time for the reporting period. This facility is not required to have any Continuous Monitoring systems (CMS).

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates

Beginning: January 01, 2008

Ending: June 30, 2008

(D) Description of Process Units

The facility process units are sterilization process chambers of various sizes using ethylene oxide gas as the sterilant. High concentration ethylene oxide process emissions are vented to an acid-water scrubber and low concentration ethylene oxide emissions are exhausted to a catalytic oxidizer abator.

(E) Emission and Operating Parameter Limitations Specified in Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Abator	Catalytic bed temperature	Continuously monitor; >240°F
Scrubber	Scrubber tank liquid level	Record weekly

(F) Monitoring Equipment Manufacturers and Model Numbers

Monitoring Equipment	Model Number	Serial Number
Honeywell Chart Recorder	Truline DR450T	8939760945047

(G) Date of Latest CMS Certification or Audit
07-07-08 (Semi-Annual Calibration)(H) Total Operating Time of Affected Source during Reporting Period
Continuous, for a total of 4188 hours.(I) Emission Data Summary

Control Unit	Total Duration of Excess Emissions	Excess Emission Duration as % of Total Hours	Excess Emission Duration by Cause				
			Startup/Shutdown	Control Equipment Problems	Process Problems	Other Known Causes	Other Unknown Causes
Abator	0 hr	0%	0	0 hrs ¹	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

<u>CMS Unit</u>	<u>Total CMS Downtime</u>	<u>Total CMS Downtime as % of Total Hours</u>	<u>CMS Downtime by Cause (hours)</u>				
			<u>Monitoring Equipment Malfunctions</u>	<u>Nonmonitoring Equipment Malfunctions</u>	<u>Quality Control Calibrations</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Honeywell Chart Recorder	0 hr	0%	0	0	0	0	0

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
None.

(L) Responsible Official Certification
Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

KA Hoffman

Kathleen Hoffman
Vice President – RA/QA

(M) Date of Report
July 17, 2008

If you have any questions regarding this report, please call Kathleen Hoffman at (630) 928-1758 or KHoffman@Sterigenics.com.

Sincerely,

KA Hoffman

Kathleen Hoffman
Vice President – RA/QA

Cc: Ms. Mary Uhl
Program Manager, Compliance and Enforcement Section
State of New Mexico, Environment Department
Air Quality Bureau
PO Box 26110
Santa Fe, NM 87502-0110



AC/A/10

1100004725

NS 41
v2

July 24, 2007

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RECEIVE

JUL 30 2007

Air/Toxics & Inspection
Coordination Branch
R6MLA

**RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring
System Performance**
Sterigenics Santa Teresa, NM Plant
January 1, 2007 to June 30, 2007

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was twelve (12) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours, which is less than 5 percent of the total operating time for the reporting period.

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide



110000472541

AI/AI/CO

NS91

V2

July 28 2006

Director, Air, Pesticides and Toxics

EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RECEIVE

AUG 1 2006

Air/Toxics & Inspection
Coordination Branch
6EN-A**RE: Summary Report****Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics US, LLC - Santa Teresa, NM Plant**

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours which is less than 5 percent of the total operating time for the reporting period.

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: January 1, 2006
Ending: June 30, 2006



AI/AI/CO

110000422541

NM
V4

RECEIVE

AUG 4 2009

Air/Toxics & Inspection
Coordination Branch
REN-A

July 30, 2009

Air, Pesticides and Toxics
Director
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System Performance
Sterigenics Santa Teresa, NM Plant
January 01, 2009 to June 30, 2009

Dear Director:

As required by 40 CFR 63.366(a)(3), Sterigenics US, LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Santa Teresa, NM plant.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Santa Teresa plant because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours, which is less than 5 percent of the total operating time for the reporting period. This facility is not required to have any Continuous Monitoring systems (CMS).

Sterigenics US, LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide

RECEIVED

AUG 4 2009

Air/Toxics & Inspection
Coordination Branch
RPN-A

- (C) Reporting Period Dates
Beginning: January 01, 2009
Ending: June 30, 2009

- (D) Description of Process Units
The facility process units are sterilization process chambers of various sizes using ethylene oxide gas as the sterilant. High concentration ethylene oxide process emissions are vented to an acid-water scrubber and low concentration ethylene oxide emissions are exhausted to a catalytic oxidizer abator.

- (E) Emission and Operating Parameter Limitations Specified in Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Abator	Catalytic bed temperature	Continuously monitor; >240°F
Scrubber	Scrubber tank liquid level	Record weekly

- (F) Monitoring Equipment Manufacturers and Model Numbers

Monitoring Equipment	Model Number	Serial Number
Honeywell Chart Recorder	Truline DR450T	8939760945047

- (G) Date of Latest CMS Certification or Audit
November 18, 2008 (Semi-Annual Calibration)

- (H) Total Operating Time of Affected Source during Reporting Period
Continuous, for a total of 4166 hours.

- (I) Emission Data Summary

Control Unit	Total Duration of Excess Emissions	Excess Emission Duration as % of Total Hours	Excess Emission Duration by Cause				
			Startup/Shutdown	Control Equipment Problems	Process Problems	Other Known Causes	Other Unknown Causes
Abator	0 hr	0%	0	0 hrs ¹	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

CMS Unit	Total CMS Downtime	Total CMS Downtime as % of Total Hours	CMS Downtime by Cause (hours)				
			Monitoring Equipment Malfunctions	Nonmonitoring Equipment Malfunctions	Quality Control Calibrations	Other Known Causes	Other Unknown Causes
Honeywell Chart Recorder	0 hr	0%	0	0	0	0	0

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
None.

(L) Responsible Official Certification
Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

KA Hoffman

Kathleen Hoffman
Vice President – RA/QA

(M) Date of Report
July 30, 2009

If you have any questions regarding this report, please call Kathleen Hoffman at (630) 928-1758 or KHoffman@Sterigenics.com.

Sincerely,

KA Hoffman

Kathleen Hoffman
Vice President – RA/QA

Cc: Ms. Mary Uhl
Program Manager, Compliance and Enforcement Section
State of New Mexico, Environment Department
Air Quality Bureau
PO Box 26110
Santa Fe, NM 87502-0110



October 6, 2015

Donald M. Smith
6EN-AS
U.S. Environmental Protection Agency
Region 6
Compliance Assurance and Enforcement Division
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202

RECEIVE

OCT 8-2015

Air/Toxics & Inspection
Coordination Branch
6EN-A

Dear Mr. Smith:

This letter is in response to the email you sent to Mr. Steve Ortiz, the General Manager of Sterigenics Santa Teresa facility on September 24, 2015. Following are the responses to the questions regarding the ethylene oxide (EO) release at the Santa Teresa facility on September 14, 2015.

1. **Provide the name, title, email, phone number and mailing address for the person to whom correspondence should be sent regarding the release.**

Kathleen Hoffman
Sr. Vice President – Global EH&S
2015 Spring Road, Suite 650
Oak Brook, IL 60523
630-928-1758
Khoffman@sterigenics.com

2. **Who owns and/or operates the location where the event occurred?**
Sterigenics U.S., LLC

3. **Briefly describe the facility, e.g. discuss what activities take place on-site and what substances are produced, processed, handled or stored on-site.**

This facility performs batch sterilization of medical products and bioburden reduction of spice products using ethylene oxide (EO). On occasion, propylene oxide (PO) is used to treat various nut products. EO is stored in 400-pound cylinders. The maximum quantity of EO at this facility is 20,000 pounds or 50 cylinders. The medical supplies and/or spices are placed in the sterilization chambers on pallets where the EO is introduced. Upon completion of the sterilization cycle, EO is removed from the sterilization chamber and routed to an emission control system, which destroys the EO. The pallets are then removed from the sterilization chambers and placed in an aeration room. The aeration room is a high-temperature with continuous air-flow environment that allows the treated product to off-gas residual EO. The emissions from the aeration room are routed to a catalytic oxidizer for destruction.

- 4. What process units or equipment were involved in the event? Provide a brief description and process flow diagram for the processes involved.**

Sterilization Chamber #2 was involved in the incident. For further information, please refer to the attached process flow diagram.

- 5. At the time of the incident, was the facility operating under a Title V Air Permit?**

This facility operates under state permit No. 0733-M15-R1 issued by the New Mexico Air Quality Bureau. The facility does not meet the applicability criteria for a Title V permit and thus was not issued a Title V permit by the permitting agency.

- 6. What is the SIC or NAICS code for the facility where the event occurred?**

The facility's SIC code is 7389 and NAICS code is 561910.

- 7. Did the event take place at a Risk Management Program covered process?**

Yes, the process is covered by the Risk Management Program.

- 8. Provide a detailed description and timeline of the event. Include the best known start time and duration of the incident and the timeline for any emergency response.**

The release was caused by the Chamber #2 door hand wheels not being tightened sufficiently during the sterilization cycle. This caused the EO to escape the chamber and activated local Lower Explosive Limit (LEL) alarms. The plant was evacuated in response to the LEL alarms. After building evacuation, responding facility employees donned proper personal protective equipment (PPE) and re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. The release began at approximately 7:40 am and ended around 8:10 am PST. The duration of the incident was approximately 30 minutes.

- 9. What specific substances were released during the event, including the estimated or known amounts of each substance? Include all air contaminants that were released during the event, even those materials with release amounts below the reportable quantity.**

We estimate that about 37 pounds of EO vapor was released inside the facility from Sterilization Chamber #2. The facility has exhaust fans that vent indoor air directly to atmosphere from the roof. In addition, Chamber #2 is located adjacent to the aeration room which has a negative pressure and draws some air from the chamber room into the aeration room. The aeration room is controlled by a catalytic oxidizer with a minimum control efficiency of 99%. We estimate approximately 10% of the EO released during this event, or about 4 pounds, vented through the aeration room and catalytic oxidizer. Therefore, the total EO released to the atmosphere would be 0.04 pounds via the catalytic oxidizer and 33 pounds to the outside environment via the exhaust fans.

10. Have there been any investigations or audits of the event? Are investigations or audits pending? Who performed the investigations or audits? Provide a copy of the reports, audits, or any other analysis describing the causes and consequences of the event, including all draft reports and/or draft audit results.

Sterigenics has conducted an internal investigation into the EO release event. The internal investigation of this event included Operations, Global EH&S, Global Engineering, and SteriPro Lab. A copy of the initial EO release report is included. A more detailed investigation report with corrective actions is also being developed.

11. What is the initial best known cause or root cause of the event? Were there any additional contributing factors that you are aware of?

The root cause for this EO release was the Chamber 2 door hand wheels not being tightened sufficiently during the sterilization cycle. A key contributing factor was that this sterilization cycle operated under positive-pressure conditions during the injection of EO into the chamber. Another contributing factor is that this positive pressure cycle was being operated in sterilization chambers with manual doors.

12. What measures have been taken to address the findings, conclusions or recommendations of the investigations or audits?

As an immediate corrective action taken within 30 minutes of the incident occurring, the chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. Based on our investigation, the following list of additional corrective actions and expected completion dates:

- Review incident with all facility employees and response to incident to identify any areas for improvement - Complete
- Review incident and investigation with all Sterigenics locations – October 30, 2015
- Limit the operation of this cycle to chambers with automated doors and gaskets to ensure doors are properly locked until further controls, described below, are implemented on applicable manual chambers – Complete
- Install equipment to implement chamber door hand wheel tightening notification system for manual chambers – Complete
- Implement tracking log system where two operators confirm and verify the tightening of the manual doors – Complete
- Review safety concerns with customer and see what they can do to minimize the product sterilized with the positive-pressure cycle and confirm a timeline for the elimination of this cycle – October 9, 2015
- Modify leak or emergency procedures to immediately estimate release amount for all events that trigger an LEL alarm – December 30, 2015
- Inventory all positive-pressure sterilization cycles and perform risk assessment – October 30, 2015

19. Identify and provide copies of any industry standards, internal standards, SOPs, or manufacturer's recommendations related to the incident including equipment, process units, and personnel activities involved in the incident.

Sterigenics has a number of standard operating procedures for the operation of its sterilization equipment and its environmental, health and safety procedures. In addition, the facility and its process equipment is built to applicable industry standards. One specific internal standard applicable to this EO release event is the Emergency Operating Procedure for High level EO Alarms (EOP-050). Attached is a copy of this procedure.

20. Please provide any documents associated with the identification of hazards at your facility related to the incident.

Sterigenics has a number of risk assessment tools that are used to identify hazards associated with our process and operations. We have an EHS procedure "Hazard Identification – Risk Assessment" (EHS-201) that outlines all such risk assessments. Attached is a copy of this procedure. One critical risk assessment is the Process Hazard Analysis (PHA) for the EO process at the Santa Teresa facility. This is completed and updated within our Process Safety Management and Risk Management Program. To better understand the specific hazards associated with ethylene oxide, also attached is the ethylene oxide Safety Data Sheet.

21. Has any local, state, or federal agency conducted an investigation or requested information regarding the event? If so, please provide the name and contact information for each agency person who conducted an inspection or requested information.

Per emergency notification requirements in 40 CFR 302.6 and 40 CFR 355.40, upon discovering the potential release was likely greater than the 10-pound reportable quantity and in accordance with notification requirements in 40 CFR §302.6 and 40 CFR §355.40, facility personnel immediately notified the following agencies of the release:

- National Response Center (NRC) (Case # 1128845)
- Dona Ana County/Las Cruces LEPC, and
- New Mexico State Emergency Response Commission (SERC)

In addition, we submitted a follow up letter in accordance with 40 CFR §355.40 to Mr. David Almaguer of the Dona Ana County/Las Cruces LEPC and Ms. Susan Walker and Mr. Henry Jolly of the NM SERC. We have not received notice of any investigation that has been conducted. A copy of the follow up letter is attached for your reference.

Attachment 1: Process Flow Diagram

Attachment 2: Initial EO Release Report



SPILL AND RELEASE INVESTIGATION REPORT

NOTE: COMPLETE THIS FORM WHENEVER THERE IS A SPILL OR RELEASE OF A HAZARDOUS SUBSTANCE INCLUDING ETHYLENE OXIDE

A. Facility Originating Report

Facility: Santa Teresa	Phone: 575-589-9300
Address: 2400 Airport Rd	City/State/Prov.: Santa Teresa, NM 88008

B. Incident Description

1. Date/Time

Start Date: 14-Sep-2015	End Date: 14-Sept-2015	
Start Time: 7:42 am	End Time: 8:08 am	Total Time: 00:26 min

2. Environmental Conditions (check all that apply)

Location of Spill/Release: Chamber 1 and 2 vault	
Spill/Release onto or into: <input checked="" type="checkbox"/> Air <input type="checkbox"/> Ground <input type="checkbox"/> Water	Release Occurred: <input checked="" type="checkbox"/> Indoors <input type="checkbox"/> Outdoors
Weather type: <input type="checkbox"/> Overcast <input checked="" type="checkbox"/> Sunny <input type="checkbox"/> Precipitation	Wind Direction and Speed: SSE at 8.1 mph

3. Substance Description:

Name of Substance Spilled/Released: Ethylene Oxide	
Amount(s) Spilled/Released: Undetermined	Amount Recovered: TBD
Extremely Hazardous Substance? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Reportable Quantity of Substance: 10 lbs
Source Container: Sterilization Chamber 2	Capacity of Container: 13 Pallet Chamber
Brief Description of Incident: During processing in Ch.2, in Gas Inject A, the door hand wheels on rear door were not tightened sufficiently. This caused EtO to escape the Chamber into Chamber Module Room and activated a 30% LEL alarm.	
Corrective Actions Taken: Plant evacuated and Facility Employees first responders donned PPE and re-entered the facility and tightened door wheels to mitigate the leak.	

C. Notifications

Entity Notified	Phone No.	Time/Date of notification	Person notified
Corporate EHS	630-928-1700	Approx: 8am 14 Sep 15	Juan Segovia
National Resp Center	800-424-8802	3:45 pm 18 Sep 2015	Operator on Duty
Office of Emerg/Mgmt	575-647-7900	3:48pm 18 Sep 2015	David Almaguer
NM Emergency Response Comm	505-476-0617	3:50pm 18 Sep 2015	Henry Jolly/ Left Voicemail

D. Review and Approval

	Print Name	Signature	Date
Spill Report Prepared by	Stephen Ortiz		21 Sep 15
Facility (General) Manager	Stephen Ortiz		21 Sep 15

Attachment 3: Emergency Operating Procedure for High EO Level Alarms
(EOP-050)



Emergency Operating Procedure

High Level EO Alarms

Document N°

EOP-050

Revision N°

1

Effective Date

29 Mar 2013

I. SCOPE

A release of ethylene oxide (EO) is a potential health and physical hazard. Since EO is an odorless gas, a leak can go undetected if not properly monitored. Each Sterigenic's EO facility uses both area monitoring devices and LEL sensors. This procedure describes the action to be taken in response to an EO release within a Sterigenics facility. The following situations are addressed within this procedure: (A) 50-ppm alarm response, (B) LEL alarm response, (C) Facility Evacuation, and (D) False Alarms.

II. APPLICATION

This standard applies to all Sterigenics EO facilities.

III. EMERGENCY LEADER

The Emergency Leader (EL) must have training completed under EHS-105 *Emergency Action Planning* and the applicable EOPs. The EL will be the first person from the following list:

- 1) General Manager
- 2) Facility EH&S Coordinator
- 3) Operations Manager
- 4) Quality Assurance Manager
- 5) Process Supervisor
- 6) Maintenance Supervisor
- 7) Shift Leader or Most Senior Operator

IV. EQUIPMENT REQUIREMENTS

1. The following equipment should be assembled and maintained at all times in an Emergency Kit:
 - Portable EO monitor (e.g. PID (Photo Ionization Detector) or Draeger charcoal tubes with pump) – charged, calibrated, and operational as applicable
 - Hand Held LEL Meter – charged, calibrated, and operational
 - Communication Device (intrinsically safe)
 - Most current SDS for EO
 - Facility Map
 - Emergency Call List
2. The following protective equipment for emergency response must be provided in a safe access area near an exit to the facility:
 - SCBA (2 pair of 2 units must be readily available and operational)
 - Chemical Suit (DuPont CPF 3 or equivalent)
 - Butyl Rubber or Nitrile Rubber gloves

V. DEFINITIONS

- SCBA – Self Contained Breathing Apparatus
- SDS – Safety Data Sheet (Previously known as an MSDS or Material Safety Data Sheet)

VI. PROCEDURE

1. Evacuations:

- A. **Area Evacuations:** An area evacuation is necessary when GC area monitoring levels exceed 50ppm or an LEL sensor reports above 10% but below 25%. (Because of current GC limitations, EMEAA facilities do not have to formally respond and document area evacuations. However, they should investigate and respond to any elevated EO levels.)
 - a. Evacuate unnecessary employees and visitors from the affected area to a safe location either inside or outside the facility at a designated location.
 - b. The General Manager and/or Emergency Coordinator must determine the appropriate



Emergency Operating
Procedure

High Level EO Alarms

Document N°	Revision N°	Effective Date
EOP-050	1	29 Mar 2013

response strategy and deem the area safe for entry by confirming readings via the door interlock panelview or the Zellweger LEL detection central.

- c. Responders must wear appropriate PPE and use a PID and handheld LEL to enter the evacuated area.

B. Facility Evacuations: A building evacuation is necessary when EO levels equal or exceed 25% LEL.

- a. Leave the building by means of the closest safe emergency exit.
- b. Reference EOP-006 *Facility Evacuation*.
- c. Check the wind direction to ensure the evacuation assembly location is safe and not downwind of an EO release.

2. EO Alarm Responses:

- A. Some local fire departments require immediate notification in the event of an EO leak or alarm. If this is not done automatically via the alarm system, the Emergency Coordinator must make the notification.
- B. When an area evacuation occurs (EO Levels < 25%), the local emergency coordinator can lead the situation but should contact the GM for guidance or advice. The GM is responsible to ensure a report describing the event is provided to corporate EHS, Engineering & Operations within 1 business day after the event.
- C. Whenever a facility evacuation occurs (EO Levels > 25% LEL), a corporate representative should be immediately contacted to participate in the response. The Emergency Coordinator must contact the first available corporate person, from the following list:
 - 1) SVP – Global EH&S
 - 2) SVP – Engineering
 - 3) VP – Operations
 - 4) Director – EH&S

If no one can be reached within 15 minutes or circumstances so dictate, the Emergency Leader may proceed to deal with the situation using local resources. The role of the corporate representative is to provide guidance & leadership to the Emergency Leader. The corporate representative becomes responsible to contact any additional corporate resources needed if they may not have the knowledge or experience to lead the situation.

- D. EO levels which require facility evacuation will have an audible alarm, which can be heard throughout the facility. A Visual Warning signal may also be present. See Section F of this procedure.
- E. Evacuate all staff from the affected area using the closest safe exit (per EOP-006). Note: EO levels below 25% LEL do not require total facility evacuation, only the affected area as determined by the Emergency Leader.
- F. If/when safe to do so, an EO Operator will stop any cycles that are in progress. An E-Stop button is provided on the Door Interlock panel which will stop all chambers (or next to the Zellweger LEL detection panel which also closes all of the EO valves). If EO levels in the Control Room are unsafe, evacuate and re-enter with appropriate PPE as directed by the Emergency Leader.
- G. If the Emergency Leader deems it safe, two trained employees, wearing an SCBA, Chemical Resistant Suit and Butyl Rubber gloves ("response team") can re-enter the facility to check the displays showing LEL and EO area levels
- H. If the Emergency Leader deems it safe, the response team may enter the suspected leak area to investigate the cause of the high EO levels.
- I. In concentrations of up to 10,000 ppm EO (33% LEL), SCBA is permitted for extended use. In concentrations up to 50% LEL (15,000 ppm), SCBA can only be used for 15 minutes.



Emergency Operating Procedure

High Level EO Alarms

Document N°

EOP-050

Revision N°

1

Effective Date

29 Mar 2013

6. EO Warning Lights – EMEAA Facilities:

Color	Area Stack Light	LEL Siren	Action Expected	Area GC System	LEL Level
			Plant Evacuation Call Corp		>25%
RED	Constant - ALL	Silent	Area Evacuation	≥ 5 ppm	
RED	Constant - Local	Silent	Area Evacuation. Handheld measurements	Not measuring correctly.	
YELLOW	Constant - Local	Silent	PPE or max 15 min in area?	≥1 ppm	
GREEN*	Constant - Local	Silent	All Clear	None Detected	

* Some facilities do not have a green light. For these facilities, the absence of Yellow and Red Lights in this case would signify Green.

7. EO Facility Alarm and Evacuation Guide

When Evacuating:		When Responding:	
<ul style="list-style-type: none">• Evacuate facility ASAP using nearest safe exit• Gather in designated assembly area.• Bring EOPs, evacuation kit and visitor list.• Ensure evacuation area is upwind from facility. If not, move to alternate assembly area.• Contact facility management & corporate.		<ul style="list-style-type: none">• ALWAYS use Buddy system when levels > 50 ppm.• Respond using correct PPE (e.g. SCBA, gloves, chem. Resistant suit).• Bring PID, LEL meter & explosion-proof communication tool.• Only use spark-proof tools in response to any EO leak.• Ventilate the affected area when possible.	
ALARM CONDITION		RESPONSE	
Area Monitor: < 1 ppm	No Action Required. If levels occur in an office or control room, check ventilation systems.		
Area Monitor: 1 - < 3 ppm	PPE Requirement: Canister respirators in affected area if > 15 min. <ul style="list-style-type: none">• Check engineering controls to ensure they are working properly.		
Area Monitor: 3 - 50 ppm	PPE Requirement: Canister respirators (in affected area) <ol style="list-style-type: none">1. Use PID to confirm levels and investigate source.2. Check engineering controls to ensure they are working properly.		
Area Monitor: > 50 ppm (excludes aeration rooms)	PPE Requirement: SCBA, chemical-resistant suit & gloves (in affected area) <ol style="list-style-type: none">1. Evacuate unnecessary employees and visitors from the affected area.2. Use PID to confirm levels and to investigate source.3. Check engineering controls are working properly. Ventilate area.		
ALARM CONDITION		RESPONSE	
LEL Alarms: 10 - 25% LEL (10% LEL = 3,000 ppm)	PPE Requirement: SCBA, chemical-resistant suit & gloves (in affected area) <ol style="list-style-type: none">1. Evacuate unnecessary employees and visitors from the affected area.2. Use PID and handheld LEL meter to investigate source.3. Check engineering controls are working properly. Ventilate area.4. E-mail report on incident to corporate within 1 business day of the incident.		



Emergency Operating Procedure

High Level EO Alarms

Document N°

Revision N°

Effective Date

EOP-050

1

29 Mar 2013

LEL Alarms: 25 – 50% LEL (25% LEL = 7,500 ppm)	PPE Requirement: SCBA, chemical-resistant suit & gloves (in affected area) 1. EVACUATE ALL EMPLOYEES AND VISITORS IMMEDIATELY. 2. Contact Corporate. 3. Enter affected area with handheld LEL & PID, proceed slowly watching readings; 4. Stay in area for ONLY up to 15 Minutes, then evacuate and make notifications to EHS/Eng. • If EO source can't be located – evacuate & await instructions. • If source is located (e.g. valve leak), use extreme care. Attempt to stop EO leak if possible to complete within 15 mins. 5. If containment is not possible, Responders should evacuate immediately. 6. E-mail report on incident to corporate within 1 business day of the incident.
LEL Alarms: 50 – 70% LEL (50% LEL = 15,000 ppm)	1. Response team may only view the PanelView to assess if not in affected area. 2. Call 9-1-1 (Fire Department) immediately.
LEL Alarms: > 70% LEL	DO NOT RE-ENTER FACILITY. Call 9-1-1 (Fire Department) immediately!
Facility Fire Alarm	1. EVACUATE ALL EMPLOYEES AND VISITORS IMMEDIATELY. 2. Call 9-1-1 immediately to ensure Fire Department has been notified; and 3. If small non-EO fire, trained employees can put it out with extinguishers. 4. Consider start of deluge system on EO drum storage if fire is nearby.
Man Down	1. Call 9-1-1 immediately and stay with employee if safe to do so. 2. Respond with appropriate PPE (buddy system, if > 50 ppm). 3. Have someone meet emergency medical help in parking lot. 4. Move injured employee to a safe area if in exposure area and if safe to do so. Over 600 ppm of EO is IDLH (Immediately Dangerous to Life/Health).
Leaking EO Drum	1. DO NOT move leaking drum. Call Corporate EH&S and Engineering immediately. 2. For full drum, evacuate plant & discuss immediately with EHS and/or Engineering. 3. If release is greater than 10 pounds (in US Only), contact National Response Center at 800-424-8802 and local fire department (after agreement with Corporate EH&S). 4. For empty drum, follow guidance for appropriate EO levels detailed above.

VII. REVISION HISTORY

Revision	Section	Description of Change
1	ALL	Reformatted to MERLIN template Procedure rewritten to become a global standard

Attachment 4: Risk Assessment Procedure

EHS-201



Hazard Identification – Risk Assessment

Global EH&S Standard

Document N°

EHS-201

Revision N°

2

Effective Date

30 Sep 2015

Approval:

Signature on File

I. PURPOSE

Hazard Identification and Risk Assessment (HI-RA) is a process to identify workplace hazards with the potential to cause safety, health and environmental harm, assessing the hazard for its risk potential and managing the risk to an acceptable or tolerable level. The overall objective of this process is to identify, analyze, evaluate, manage, communicate and monitor hazards and their associated risk(s).

The purpose of this standard is to provide another process a facility may choose to use for assessing and mitigating workplace hazards when other established processes, such as Job Safety Analysis, and Pre-Task Safety Plans, are not suitable for managing certain facility hazards.

II. SCOPE

This standard applies to all Sterigenics locations worldwide.

III. RESPONSIBILITIES/ROLES

Facility Management	Management, upon completion of an initial HI-RA process, must establish a schedule or frequency to reassess and update facility risk assessments, such as annually.
Supervisors, EHS Committee Members, Engineering/Maintenance and the Facility EHS Representative	Supervisors, EHS Committee Members, Engineering, Maintenance and the Facility EHS Representative are trained and actively engaged in the HI-RA process to ensure effectiveness.
Employees and Visitors	May participate and actively engage in the hazard identification process and suggest potential control measures.

IV. PROGRAM ELEMENTS

HI-RA referred to in Sterigenics Corporate EH&S Standards

- a. Sterigenics uses a variety of HI-RA processes as outlined in the following corporate EHS Standards. Each facility is encouraged to use the following summary when implementing specific corporate standards:

Standard Number	Standard Name	Suggested Worksheet Referenced	Risk Matrix
EHS-101-F2	Job Safety Analysis (JSA)	EHS-101-F2 Job Safety Analysis	N/A
EHS-101-F3	Pre-Task Safety Plan (PTSP)	EHS-101-F3 Pre-Task Safety Plan	N/A
EHS-202	Machine Safeguarding	EHS-202-F1 Risk Assessment Form	EHS-202-F1 Risk Assessment Form
EHS-401	Personal Protective Equipment (PPE)	EHS-401-F1 PPE Assessment Form	N/A
EHS-801	Ethylene Oxide – General Requirements	EHS-801-F1 EO Risk Assessment Form	EHS-801-F1 Risk Assessment Form
EHS-901	Process Safety Management (PSM)	<ul style="list-style-type: none">What If ChecklistHazard and Operability Study (HAZOP)	Sterigenics Risk Matrix
EHS-902	Control of Major Accident Hazards (SEVESOII/COMAH)	<ul style="list-style-type: none">What If ChecklistHAZOPFailure Modes and Effects Analysis (FMEA)	Sterigenics Risk Matrix
EHS-910	Management of Change	G-F-ENG-035 Engineering Change Record (ECR)	N/A
EHS-950	Pre-Start Up Safety Review (PSSR)	EHS-950-F1 PSSR	N/A



Global EH&S Standard

Hazard Identification – Risk Assessment

Document N°

EHS-201

Revision N°

2

Effective Date

30 Sep 2015

HI-RA not covered by Sterigenics Corporate EH&S Standards

- a. Sterigenics facilities may evaluate other tasks, projects, or customer product sterilization using the Sterigenics Hazard Identification -Risk Assessment form (EHS-201-F1) or equivalent. This risk assessment can be used to initially evaluate the risk and generate recommendations.
- b. The risk assessment can be used for the following at a minimum:
 - Proposed projects to determine regulatory impact
 - Proposed projects with the potential for property, facility or employee impact
 - Customer products with unique biological hazards
 - Customer products with unique chemical properties with a potential impact during sterilization (flammable, combustible, corrosive)
 - Customer products with a unique design (i.e., stored pressure) or workplace hazard
- c. This risk assessment may be completed by a combination of facility or corporate representatives. However, the risk assessment must be reviewed and approved by Corporate EH&S.

Conducting the Risk Assessment and using the Risk Matrix

- a. Each facility performing a risk assessment not covered under a specific EH&S corporate standard should use EHS-201-F1 and the Sterigenics Risk Matrix (included in EHS-201-F1) or equivalent to determine the risk ranking.
- b. Risk is analyzed by combining estimates of consequences and likelihood. Consequences and likelihood should consider facility and company history of incidents, equipment failure records, design criteria, statistical analysis and calculations, where available. Alternatively, where no past data are available, subjective estimates may be made which reflect an individual's or groups's degree of belief a particular event or outcome can occur.
- c. The HI-RA team should identify hazards and evaluate risk in the following manner:
 - Initially, identify hazards associated with the project or task.
 - Identify the existing controls (engineering design, training, maintenance, inspections, work instructions, procedures, and Personal Protective Equipment (PPE)) and assign a risk ranking.
 - Identify recommendations needed to reduce risk to a lower or acceptable level.
 - Lastly, recommendation(s) generated by the risk assessment should be evaluated and followed up to completion. Low and accepted risks should be monitored and periodically reviewed to ensure they remain acceptable.
 - When a significant or serious risk is assessed to be not desirable or unacceptable, it should be prioritized and managed.

V. TRAINING

Training

Individuals who are involved in the identification of hazards and assessing risk should understand the basics of the hazard identification and risk assessment process. Training must be provided to employees per the EHS training calendar.

NOTE: Corporate EH&S will provide training to facility employees that use the EHS-201-F1.



Global EH&S Standard

Hazard Identification – Risk Assessment

Document N°

EHS-201

Revision N°

2

Effective Date

30 Sep 2015

VI. REFERENCES

Document Number	Document Title
-----------------	----------------

EHS-201-CR	Hazard Identification –Risk Assessment Corporate Requirements
------------	---

EHS-201 – F1	Sterigenics Hazard Identification – Risk Assessment Form and Sterigenics Risk Matrix
--------------	--

VII. DEFINITIONS/ABBREVIATIONS

Hazard	Source or situation with a potential for harm in terms of injury or ill health, damage to property, damage to the workplace environment, or a combination of these. Hazards can include machinery, equipment, work area design or layout, and in general, any work activity used to conduct company business.
Hazard Identification and Risk Assessment (HI-RA)	A process to identify hazards, assesses risk, and implements necessary control measures. This system addresses routine and non-routine activities, functions and processes within the workplace. HI-RA includes a systematic process used in decision-making and continuous improvement with <u>prevention</u> as the primary objective in performing a HI-RA. The HI-RA process is a careful examination of the work environment to determine what could cause harm and to review if adequate precautions are in place to prevent harm. The process can be applied at all stages in the life of an activity, function, project, product or asset.
Risk	Combination of the likelihood and severity of a specified hazard occurring.
Significant or Serious Risk	A risk where additional control measures (e.g., engineered or administrative) are required to eliminate or reduce the risk to a level which is comparable with other accepted business risks (tolerable or acceptable risk). . Examples of serious risk can include the following: air and water emissions; waste generation; chemical, radiation, and biological exposures; physical hazards; ergonomic hazards; and work-related incidents.
Tolerable or Acceptable Risk	A risk reduced to an acceptable (sometimes referred to as “tolerable”) level to the facility—taking into consideration the company EHS policy and local regulatory and legal consequences.



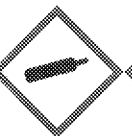

VIII. REVISION HISTORY

Revision	Section	Description of Change
2	IV. b	Clarification added to risk assessment applications
	V	Added reference to EHS training calendar
1	All	Complete rewrite of the entire procedure

Attachment 5: Safety Data Sheet for Ethylene Oxide (EO)

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER			
1.1. GHS product identifier.	Ethylene Oxide		
Other means of identification.	Oxirane		
1.2. Recommended use and restrictions on use.	<p>Recommended: Chemical intermediate for production of anti-freeze, polyester resins, non-ionic surfactants and specialty solvents; sterilizing agent for controlling microorganisms in health care applications; fumigant for controlling insect infestation in whole and ground spices and cosmetics; sterilization of musical wind instruments.</p> <p>Advised Against: Consumer use.</p>		
1.3. Supplier's details.	<p>Name: ARC Specialty Products c/o Balchem Corporation Address: 52 Sunrise Park Road New Hampton, NY 10958 USA Phone number: +1 845-326-5611 Fax number: +1 845-326-5706 Internet: www.arcspecialtyproducts.com Email: sds@balchem.com</p>		
1.4. Emergency phone number.	<p>EMERGENCY TELEPHONE (24 hrs. / 7 days per week)</p> <p>In Canada: CANUTEC (613) 996-6666 In US: CHEMTREC (800) 424-9300 Outside US & Canada: CHEMTREC (703) 527-3887</p>		

2. HAZARDS IDENTIFICATION	
2.1. GHS classification of the substance or mixture and any national or regional information.	<p>Flammable Gas 1 Pressurized Gas (Liquefied Gas) Carcinogen Category 1B Mutagen Category 1B Acute Toxicity Category 3 (Inhalation); Category 4(oral) Eye Irritant Category 2A Specific Target Organ Toxicity – Single Exposure 3 Skin Irritant 2</p>
2.2. GHS label elements, including precautionary statements.	<p>Product Label Name: ETHYLENE OXIDE Signal Word: DANGER</p> <div style="display: flex; justify-content: space-around; align-items: center;">     </div> <p>Hazard statement:</p> <p>H220: Extremely flammable gas. H280: Contains gas under pressure; may explode if heated H302: Harmful if swallowed H315: Causes skin irritation H319: Causes serious eye irritation H331: Toxic if inhaled H335: May cause respiratory irritation</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
	<p>H340: May cause genetic defects H350: May cause cancer</p> <p>Precautionary statement:</p> <p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.</p> <p>P261: Avoid breathing gas/vapours. P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear protective gloves/protective clothing/ eye protection/face protection.</p> <p>P281: Use personal protective equipment as required.</p> <p>P301;P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P330: Rinse mouth. P302;P352: IF ON SKIN: Wash with plenty of soap and water.</p> <p>P362: Take off contaminated clothing and wash before reuse.</p> <p>P332;P313: If skin irritation occurs: Get medical advice/attention.</p> <p>P304;P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305;P351;P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337;P313: If eye irritation persists: Get medical advice/attention.</p> <p>P312: Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P308;P313: IF exposed or concerned: Get medical advice/attention.</p> <p>P321: Specific treatment: See first aid section of SDS.</p> <p>P377: Leaking gas fire: Do not extinguish, unless leak can be stopped safely. Eliminate all ignition sources if safe to do so.</p> <p>P381:</p>		

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	P403;P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P410;P403: Protect from sunlight. Store in a well-ventilated place. P501: Dispose of contents/container in accordance with local/regional/national/international regulation.
2.3. Other hazards which do not result in classification or are not covered by the GHS.	EUH006: Explosive with or without contact with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS			
3.1. Substance:			
Chemical identity.	Ethylene Oxide		
Common name, synonyms, etc.	Oxirane, EO, EtO, Dihydroxirene, 1-2 Epoxyethane, Dimethylene Oxide, Oxane, Oxirane, Alpha/Beta-Oxidoethane, Oxacyclopropane		
CAS number, EC number, etc.	CAS#: 75-21-8; EC#: 200-849-9 (from EINECS) Chemical Family: Epoxide Formula: (CH ₂) ₂ O Molecular Weight: 44.053 g/mol		
Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.	Contains no other components or impurities which will influence the classification of the product.		
3.2. Mixture:			
The chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cutoff levels.	Chemical Identity:	Concentration:	CAS No.:
	No applicable information found (i.e. material is not a mixture).		

4. FIRST AID MEASURES	
4.1. Description of first aid measures.	<p>EYE CONTACT: Immediately flush eyes, including the entire surface of the eyes and under the eyelids, gently but thoroughly with plenty of running water for at least 15 minutes. Obtain medical attention immediately. NOTE: Never wear contact lenses when working with ethylene oxide.</p> <p>SKIN CONTACT: Immediately flush skin thoroughly with water for at least 15 minutes while removing contaminated clothing and shoes. Obtain medical attention immediately. Treat for possible cryogenic injury, if needed by warming affected areas with tepid water (wrap with a blanket if lukewarm water is not available). Wash clothing before reuse and discard contaminated leather articles such as shoes and belts.</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
	<p><u>INHALATION:</u> Remove exposed person to fresh air. If breathing has stopped, give artificial respiration then have qualified personnel administer oxygen, if needed. Get immediate medical attention.</p> <p><u>INGESTION:</u> If patient is conscious give plenty of water (minimum of two glasses) but DO NOT INDUCE VOMITING. This material is corrosive. Keep head lower than hips to avoid aspiration, should vomiting occur. Get medical attention immediately.</p> <p><u>MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:</u> Preexisting skin, eye and respiratory disorders; lung, blood, nervous system and peripheral nerve disorders.</p>		
4.2. Most important symptoms/effects.	<p><u>SIGNS AND SYMPTOMS OF OVEREXPOSURE:</u> Effects include skin, eye and respiratory tract irritation or burns. Central nervous system effects initially cause headache, dizziness and nausea and in extreme cases, unconsciousness and death. Peripheral nerve damage may result in muscular weakness, giddiness, irrational behavior and loss of sensation in the extremities. Dulling of the sense of smell may occur.</p>		
4.3. Indication of immediate medical attention and special treatment needed, if necessary.	<p><u>NOTE TO PHYSICIANS:</u> Respiratory symptoms include nausea, vomiting and irritation of the nose and throat. Pulmonary edema may occur. Respiratory effects may be delayed. Consider oxygen administration. If a chemical burn is present, decontaminate skin and treat as any thermal burn. No specific antidote is known, however consider gastric lavage and administration of a charcoal slurry.</p>		
5. FIREFIGHTING MEASURES			
5.1. Suitable (and unsuitable) extinguishing media.	<p><u>EXTINGUISHING MEDIA:</u> Carbon dioxide, dry chemical or water spray for small fires. Water spray, polymer or alcohol resistant foams for large fires. Dilution of liquid ethylene oxide with 22 volumes of water should render it non-flammable. Dilution with 100 parts water to one part of ethylene oxide vapor may be required to control build up of flammable vapors in closed systems. Water spray can be used to reduce flame intensity, cool fire-exposed containers and dilute spills to render non-flammable.</p>		
5.2. Specific hazards arising from the chemical.	<p><u>EMERGENCY OVERVIEW:</u> Colorless liquid or heavier-than-air gas with a sweet, ether-like odor. Extremely flammable liquefied gas which burns in the absence of oxygen and can explode when exposed to elevated temperatures. Toxic when inhaled. Causes severe skin and eye irritation or burns and respiratory tract irritation; effects may be delayed. Harmful if swallowed or absorbed through the skin. Contact with liquid may cause frostbite.</p>		

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>Statement of Hazards: DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.</p> <p>HAZARD RATINGS: (0 = minimum; 4 = maximum)</p> <p>HMIS Rating: Health = 3 Flammability = 4 Reactivity = 3 Personal Protection Code = X (Consult your supervisor or standard operating procedures for special handling directions.)</p> <p>NFPA Rating: Health = 3 Flammability = 4 Reactivity = 3</p> <p>UNUSUAL FIRE AND EXPLOSION HAZARDS: Ethylene oxide is dangerously explosive under fire conditions; it is flammable over an extremely large range of concentrations in air and burns in the absence of oxygen. Liquid ethylene oxide is lighter than water (floats) and vapors are heavier than air and may travel along ground long distances to sources of ignition, and then flash back. Avoid storage at warm temperatures [around 100 °F (38 °C)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 °C) under any circumstances. Containers are fitted with metallic plugs which melt and release contents when temperature increases to a range of 157-170 °F (69-77 °C). Vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 2.6%.</p>
--	---

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

5.3. Special protective equipment and precautions for firefighters.	<p>SPECIAL FIRE-FIGHTING PROCEDURES: Wear NIOSH-approved self-contained breathing apparatus (SCBA) operated in the pressure-demand mode and full chemical-resistant protective clothing. Evacuate all personnel from danger area and keep upwind. Immediately cool containers with water spray from maximum safe distance. Stop flow of gas, if without risk, while continuously cooling containers with water. Do not extinguish flames unless flow is stopped, since explosive re-ignition can occur. Remove containers from fire area, if without risk. Refer to the most current edition of the "North American Emergency Response Guidebook" for isolation and evacuation distances.</p>
---	--

6. ACCIDENTAL RELEASE MEASURES	
6.1. Personal precautions, protective equipment and emergency procedures.	<p>PRECAUTIONS: Treat any ethylene oxide leak as an emergency. All cleanup personnel must wear full protective equipment. Evacuate all personnel from the area except those directly engaged in stopping the leak or in cleaning up.</p>
6.2. Environmental precautions.	<p>ENVIRONMENTAL: Dike runoff water, if possible, to prevent contaminated water from entering sewers, ditches, streams and ponds. It is mandatory to call the National Response Center (800-424-8802) if 10 pounds (4.54 kg) or more is spilled or released to the environment.</p>
6.3. Methods and materials for containment and cleaning up.	<p>SPILL CLEANUP: Eliminate all ignition sources if this can be done safely. Ethylene oxide/air mixtures ignite readily and may detonate. Use water fog or spray to disperse vapors. Flood spill with water spray to dilute and render non-flammable.</p>

7. HANDLING AND STORAGE	
7.1. Precautions for safe handling.	<p>HANDLING AND STORAGE PRECAUTIONS: Wear all recommended protective clothing and devices when handling this material. Have established handling and emergency response procedures in place prior to use. Ground and bond shipping container, transfer line, and receiving container. Protect containers from physical damage and regularly inspect them for cracks, leaks or faulty valves.</p>
7.2. Conditions for safe storage, including any incompatibilities.	<p>STORAGE SEGREGATION: Store ethylene oxide in a cool, dry, well-ventilated area away from incompatible chemicals and sources of ignition. Store cylinders and drums upright; secure containers tightly; do not drag or slide; and move in a carefully supervised manner with a suitable hand truck. DO NOT STORE IN DIRECT SUNLIGHT.</p> <p>SHIPPING AND STORAGE CONTAINERS: (See 49 CFR 173.323) Ethylene oxide is shipped and stored in UN 1A1 specification drums and DOT specification drums and cylinders. Nitrogen must be charged into the container after filling with ethylene oxide, bringing the</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>total container pressure up to 50 psig. Before returning container to supplier, pressurize container with nitrogen to 50 psig total pressure; close valves and replace valve plugs tightly in outlets. Check container valves and plugs for leaks prior to shipment. In addition, please refer to the most current edition of NFPA Publication 55, 'Compressed Gases and Cryogenic Fluids Code.'</p> <p>INCOMPATIBILITIES: Ethylene oxide is very reactive. Runaway exothermic polymerization reactions can result from contamination with amines, ammonia, water, acids, bases, metal chlorides, metal oxides, metallic potassium, mercaptans, alcohols, oxidizers and many other organic and inorganic materials.</p>
--	--

8. EXPOSURE CONTROLS/PERSONAL PROTECTION				
8.1. Control parameters.	Exposure Limits			
	<u>SOURCE</u>	<u>TWA (8-hr)</u>	<u>STEL (15-min)</u>	<u>OTHER</u>
	OSHA	1 ppm	5 ppm (9 mg/m ³)	0.5 ppm action level (8-hr TWA)
	ACGIH	1 ppm (1.8 mg/m ³)	No applicable information found	800 ppm IDLH
8.2. Appropriate engineering controls.	<p>ENGINEERING CONTROLS: Ethylene oxide, a major fire hazard, can burn in the absence of oxygen. All electrical devices used in areas processing or handling ethylene oxide must be engineered and designed to the applicable local electrical/fire codes. Safeguards can include designing electrical devices as explosion-proof and/or intrinsically safe. When considering engineering controls, users of ethylene oxide should consult the current edition of NFPA 55 (Compressed Gases and Cryogenic Fluids Code, Section 14: Storage, Handling and Use of Ethylene Oxide for Sterilization and Fumigation). Sterilization facilities should consult NIOSH Publication NO. 2007-164 (Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities).</p> <p>VENTILATION: Install and operate general and local exhaust ventilation systems powerful enough to maintain airborne levels of ethylene oxide below the OSHA PEL in the worker's breathing area. Ventilation systems must be of maximum explosion-proof design. Emission controls must be in compliance with Federal, State and local regulations.</p> <p>SAFETY SHOWERS: Have eyewash stations, emergency deluge showers, and washing facilities available in all work areas.</p>			

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
		<p>OTHER PROTECTION: Design all engineering systems to be explosion-proof in any area where this gas may be present. Container and system must be electrically grounded/bonded before unloading. Practice good personal hygiene; always wash thoroughly after using this material. Do not eat, drink or smoke in work area.</p>	
8.3. Individual protection measures, such as personal protective equipment.		<p>RESPIRATORY PROTECTION: Refer to OSHA respirator regulations cited at 29 CFR 1910.134 and 29 CFR 1910.1047. Wear a NIOSH-approved full facepiece respirator for routine use situations where atmosphere is at or above OSHA's Action Level. Do not exceed the maximum use conditions of the respirator. For emergency or non-routine uses where concentrations are unknown, wear an SCBA with a full facepiece operated in the pressure-demand or positive pressure mode.</p> <p>EYE PROTECTION: Always wear chemical safety glasses. If splashing may occur, wear a full face shield as a supplementary protective measure over safety glasses. NEVER WEAR CONTACT LENSES when working with ethylene oxide.</p> <p>SKIN PROTECTION: Wear impervious gloves (see www.ethyleneoxide.com for permeation data); boots; aprons; head cover; and clean impervious body-covering clothing to prevent any possibility of skin contact. Launder contaminated clothing and discard contaminated leather shoes, belts, etc.</p>	

9. PHYSICAL AND CHEMICAL PROPERTIES	
9.1. Information on basic physical and chemical properties.	
Appearance (physical state, color, etc.).	Colorless liquid or gas
Odor.	Sweet ether-like
Odor threshold.	261 ppm – detectable 500 to 700 ppm - recognizable
pH.	7, neutral (100 g/L in water)
Melting point/freezing point.	-169 °F (-112 °C)
Initial boiling point and boiling range.	50.7 °F (10.4 °C)
Flash point.	Tag Closed Cup: < 0 °F (< 18 °C)
Evaporation rate.	100% volatile by volume
Flammability (solid, gas).	Flammable
Upper/lower flammability or explosive limits.	Upper flammable limit: 100% vol/vol Lower flammable limit: 2.6% vol/vol
Vapor pressure.	1095 mmHg @ 20 °C
Vapor density.	1.5 (Air = 1)
Relative density.	0.875 at 20 °C
Solubility (ies).	100% in water
Partition coefficient: n-octanol/water.	-0.3
Autoignition temperature.	833 °F (445 °C); Burns in the absence of air
Decomposition temperature.	~932 °F (~773 °K)
Viscosity.	0.255 centipoise at 80 °F
Oxidizing properties.	Not an oxidizer

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

10. STABILITY AND REACTIVITY	
10.1. Reactivity.	Not reactive under normal conditions. Under abnormal conditions (for example external heating, contamination), thermal decomposition and runaway polymerization can occur and may lead to explosion.
10.2. Chemical stability.	STABILITY: Material is stable for extended periods in closed, airtight, pressurized containers at room temperature, under normal storage and handling conditions. Vapors may explode when exposed to common ignition sources. In the presence of catalysts, polymerization and decomposition of liquid may occur and is accelerated at temperatures above 800 °F (426 °C).
10.3. Possibility of hazardous reactions.	HAZARDOUS POLYMERIZATION: Dangerous exothermic polymerization reaction can occur when ethylene oxide is contaminated or when heated.
10.4. Conditions to avoid (e.g., static discharge, shock or vibration).	CONDITIONS TO AVOID: Avoid storage at warm temperatures [around 100 °F (38 °C)] in order to prevent polymerization. Do not store at temperatures above 125 °F (52 °C) under any circumstances. Avoid contact of ethylene oxide with incompatible chemicals to avoid highly exothermic polymerization reaction. Prevent exposure to all sources of ignition such as heat, flame, lighted tobacco products or electrical or mechanical sparks.
10.5. Incompatible materials.	See section 7.2
10.6. Hazardous decomposition products.	HAZARDOUS DECOMPOSITION PRODUCTS: Ethylene oxide undergoes thermal decomposition to form carbon dioxide and carbon monoxide gases.
11. TOXICOLOGICAL INFORMATION	
11.1. Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);	PRIMARY ROUTES OF EXPOSURE: Inhalation; eye contact; skin contact/absorption.
11.2. Symptoms related to the physical, chemical and toxicological characteristics;	<p>ACUTE HEALTH EFFECTS:</p> <p>INHALATION: Inhaling concentrated vapor may cause serious health effects, possibly death. Inhalation may progressively cause mucous membrane and respiratory irritation, headache, vomiting, cyanosis, drowsiness, weakness, loss of coordination, CNS depression, lachrymation, nasal discharge and salivation, gasping, and labored breathing. Delayed effects may include nausea, diarrhea, edema of the lungs, paralysis, convulsions and possibly death. NOTE: Ethylene oxide has a high odor threshold (> 250 ppm) and the sense of smell does not provide adequate protection against its toxic effects.</p> <p>EYE CONTACT: Liquid ethylene oxide is severely irritating and corrosive to the eyes and contact can cause swelling of the conjunctiva and irreversible corneal injury. Contact with liquid ethylene oxide can cause frostbite.</p>

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
	<p>Vapors may cause eye irritation, tearing, redness and swelling of the conjunctiva.</p> <p>SKIN CONTACT: Prolonged contact with liquid ethylene oxide can cause a local erythema, edema, and formation of blisters. Response is more severe on damp skin. There may be a latency period of several hours prior to the onset of symptoms. Ethylene oxide may be absorbed by the skin, and sustained contact may produce adverse effects such as headache, dizziness, nausea and vomiting. Ethylene oxide is a skin sensitizer and some individuals may suffer an allergic skin reaction. Skin contact may also cause allergic contact dermatitis in some exposed individuals. Liquid ethylene oxide evaporates rapidly and may chill the skin causing frostbite.</p> <p>INGESTION: This relatively unlikely route of exposure is expected to cause severe irritation and burns of the mouth and throat, abdominal pain, nausea, vomiting, collapse and coma. Aspiration may occur during swallowing or vomiting, resulting in lung damage.</p>		
11.3. Delayed and immediate effects and also chronic effects from short- and long-term exposure;	<p>CHRONIC HEALTH EFFECTS:</p> <p>SKIN CONTACT: Long term effects are unknown but are expected to be similar to acute effects of skin exposure.</p> <p>EYE CONTACT: Some cases of cataract formation have been reported.</p> <p>INHALATION: Respiratory irritation which can result in permanent lung injury, chromosomal aberrations and peripheral neurotoxic effects with a numbing of the sense of smell. Cognitive and CNS impairment may result from long term exposures.</p> <p>INGESTION: May cause anemia, gastrointestinal irritation, effects on liver, kidneys, and adrenal glands.</p> <p>CARCINOGENICITY: OSHA classifies ethylene oxide as a cancer/reproductive hazard and considers that, at excessive levels, ethylene oxide may present reproductive, mutagenic, genotoxic, neurologic and skin sensitization hazards. ACGIH classifies ethylene oxide as "A2" - suspected human carcinogen. NTP classifies ethylene oxide as a known human carcinogen. IARC classifies ethylene oxide in Group I (carcinogenic to humans). NIOSH classifies ethylene oxide as a potential human carcinogen.</p>		

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

<p>11.4. Numerical measures of toxicity (such as acute toxicity estimates).</p>	<p><u>TOXICOLOGICAL - ACUTE INHALATION:</u> LC₅₀ (1 hr. exposure) 5748 ppm (male rat) 4439 ppm (female rat) 5029 ppm (rat - combined sexes) Various mammalian species exposed to lethal concentrations of ethylene oxide had symptoms of mucous membrane irritation, central nervous system depression, lacrimation, nasal discharge, salivation, nausea, vomiting, diarrhea, respiratory irritation, loss of coordination and convulsions.</p> <p><u>TOXICOLOGICAL - CHRONIC INHALATION:</u> Symptoms of chronic exposure are similar to those observed in acute studies, including lung, kidney and liver damage and testicular tubule degeneration in some species. Studies demonstrated neuromuscular effects as the most sensitive indicator of ethylene oxide overexposure.</p> <p><u>TOXICOLOGICAL - ACUTE DERMAL:</u> No dermal LD₅₀ information is available on this product. It is expected to be corrosive to rabbit skin.</p> <p><u>TOXICOLOGICAL - CHRONIC DERMAL:</u> No chronic dermal toxicity data are available on this product.</p> <p><u>TOXICOLOGICAL - EYE:</u> No eye irritation animal data are available on this product; however, it is expected to be extremely irritating to rabbit eyes.</p> <p><u>TOXICOLOGICAL - ACUTE INGESTION:</u> The acute oral LD₅₀ for this product is: 330 mg/kg, rat.</p> <p><u>TOXICOLOGICAL - CHRONIC INGESTION:</u> The effects of chronic ingestion of this product are unknown.</p> <p><u>CARCINOGENICITY:</u> A recent assessment of available epidemiology studies related to ethylene oxide concluded that the evidence indicates that ethylene oxide does not cause heart disease, an excess of cancers overall, or brain, stomach or pancreatic cancers which were seen in some animal and isolated human studies. The findings with respect to leukemia and non-Hodgkin's lymphoma are less definitive. While the majority of the evidence does not indicate that ethylene oxide causes these cancers, there are some suggestive trends. A longer follow-up of ethylene oxide was completed in 2004 to better clarify these relationships. NIOSH reported no overall elevated risk for any type of cancer or other diseases as compared to the general population, however, among those workers with very high ethylene oxide exposure (combination of exposure level and years worked); there was evidence of an elevated risk for blood</p>
---	---

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
<p>cancers among men and breast cancer among women. Two inhalation studies with rats demonstrated carcinogenic responses consisting of increased incidences of mononuclear cell leukemia, peritoneal mesotheliomas, and primary brain tumors. In 2-year inhalation studies with mice there was evidence of carcinogenic activity as indicated by dose-related incidences of benign or malignant neoplasms of the uterus, mammary gland, and hematopoietic system (lymphoma).</p> <p><u>MUTAGENICITY:</u> While ethylene oxide has demonstrated, in epidemiological studies with exposed workers, an increased incidence of chromosomal aberrations and sister chromatid exchanges, the relevance of such effects to human health hazard evaluation is currently uncertain. In rodent studies, dose related exposure to ethylene oxide induces increases in numbers of adducts in DNA and hemoglobin. Laboratory studies with mice have shown that acute exposure to ethylene oxide at 300 ppm and above caused testicular injury as evidenced by concentration-related increased embryonic deaths following mating of exposed males to non-exposed females (Dominant-Lethal Test).</p> <p><u>NEUROTOXICITY:</u> Effects are similar to those of acute (short term) exposure, namely, headaches, nausea, diarrhea, lethargy and irrational behavior. Muscle weakness, loss of sensation in the extremities and a reduction in the sense of smell and/or taste may also result. Studies on workers indicate that CNS and cognitive impairment may result from chronic exposures to ethylene oxide.</p> <p><u>REPRODUCTIVE EFFECTS:</u> Some limited epidemiological data suggests that women exposed to ethylene oxide have a greater incidence of miscarriage. A one-generation reproduction study in rats showed decreased numbers of pups at 100 ppm but not at 33 ppm. In a two-generation reproduction study involving exposure of rats to ethylene oxide vapor for 6 hrs/day, 5 days/week, there was parental toxicity at 33 ppm and 100 ppm. Post implantation losses with reduction in litter size and offspring body weight were found at 33 ppm and 100 ppm. The no-observable effect concentration for adult toxicity, offspring effect and reproductive effect was 10 ppm.</p> <p><u>TERATOLOGY:</u> Inhalation development toxicity studies with rats exposed to ethylene oxide vapor at concentrations of 50 ppm, 125 ppm and 225 ppm showed that maternal toxicity occurred at 125 and 225 ppm. Fetotoxicity, evidenced by reduced fetal body weight, occurred at all concentrations. At 225 ppm and</p>			

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

	<p>to a lesser extent at 125 ppm an increased incidence of skeletal variants was found. There was no evidence of embryotoxicity or malformations.</p> <p>TARGET ORGANS: Overexposure to this product may affect the skin, eyes, respiratory system, liver, kidneys, brain, blood, reproductive system and central nervous system.</p>
--	--

12. ECOLOGICAL INFORMATION	
12.1. Ecotoxicity (aquatic and terrestrial, where available).	<p>AQUATIC TOXICITY: Acute 96-hr. LC₅₀ data: 57-84 mg/L, fathead minnow (<i>Pimephales promelas</i>) 90 mg/L, goldfish (<i>Carassius auratus</i>) 137-300 mg/L, water flea (<i>Daphnia magna</i>) Material is slightly toxic to marine invertebrates. 48 hr. LC₅₀ in brine shrimp: 490 mg/L</p>
12.2. Persistence and degradability.	<p>CHEMICAL FATE INFORMATION: BOD₅: 0.35 p/p. BOD₁₀: 1.1 p/p. BOD₂₀: 1.3 p/p.</p>
12.3. Bioaccumulative potential.	<p>Log octanol/water partition coefficient (log K_{ow}) is low. Partitioning from water to oil is low. Bioconcentration is not expected to occur due to high water solubility and a low log K_{ow}. Ethylene oxide hydrolyzes to ethylene glycol. Biodegradation of ethylene oxide occurs at a moderate rate after acclimation (3-20% degradation after 5 days; 70% after 20 days). Biodegradation is expected in a wastewater treatment plant. Ethylene oxide has an estimated half life in the atmosphere of 105 days. EO does not readily absorb into sediments or soils and does not persist in soils; if absorbed, soil organisms will over time convert EO to glycols eliminating any persistence in the soil.</p>
12.4. Mobility in soil.	EO does not readily absorb into sediments or soils.
12.5. Results of PBT and vPvB	No applicable information found.
12.6. Other adverse effects.	No applicable information found.

13. DISPOSAL CONSIDERATIONS	
13.1. Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.	<p>WASTE MANAGEMENT/DISPOSAL: When disposed, ethylene oxide is a RCRA hazardous waste with waste code U115 (Commercial chemical product - listed for toxicity and ignitability). Waste ethylene oxide may be incinerated in an approved hazardous waste incinerator or can be biologically treated in an approved facility. DO NOT INCINERATE ANY ETHYLENE OXIDE CONTAINERS. Ethylene oxide is banned from land disposal. Dispose of waste materials in accordance with all applicable Federal, State and local laws and regulations.</p>

14. TRANSPORT INFORMATION	
14.1. UN number.	UN 1040
14.2. UN proper shipping name.	Ethylene Oxide

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
14.3. Transport hazard class (es).	<p>DOT Primary: 2.3 (Poison Gas); Secondary: 2.1 (Flammable Gas) Poison-Inhalation Hazard Zone D Reportable Quantity 10 lb (4.54 kg)</p> <p>IMO Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)</p> <p>TDG (from or within Canada) Primary: 2.3 (Toxic Gas); Secondary: 2.1 (Flammable Gas)</p> <p>Shipments of residual amounts of ethylene oxide are considered hazardous material. All facilities shipping or receiving ethylene oxide are subject to registration as a shipper of hazardous material (49 CFR 107, Subpart G). All facilities handling ethylene oxide must also maintain a written security plan (49 CFR 172.00 – 804, 49 CFR 172.704)</p>		
14.4. Packing group, if applicable.	Not applicable		
14.5. Marine pollutant (Yes/No).	No		
14.6. Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises.	See Section 7.2		
14.7. Transportation in bulk according to Annex II of MARPOL 73/78 and the IBC Code.	Product is not supplied in bulk		

15. REGULATORY INFORMATION		
15.1. Safety, health and environmental regulations specific for the product in question.		
US Federal:	CERCLA:	Section 103: Reportable Quantity – 10 lb (40 CFR 302.4)
	CWA:	Release into a waterway may require reporting to the National Response Center @ 800-424-8802 (40 CFR 116.4).
	FIFRA	<p>If this chemical is a pesticide product registered by the United States Environmental Protection Agency, it is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use.</p> <p><u>EPA Registration No. 36736-2 and EPA Registration No. 36736-8</u> DANGER! Causes eye and skin burns. Harmful if inhaled. May cause nervous system damage. Cancer hazard and reproductive hazard. May be fatal if inhaled in high concentrations. May cause irritation of the respiratory tract. May cause immediate or delayed skin irritation or blisters. May cause allergic skin reaction. Do not breathe vapor. Highly flammable liquid and gas under pressure.</p>
	RCRA:	If discarded in purchased form, this product is a listed and characteristic hazardous waste. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal whether a material containing the product or derived from the product should be classified

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

		as a hazardous waste (40 CFR 261.20-24).
	RMP:	Listed under the EPA Chemical Accidental Prevention Provisions (Risk Management Plan: 40 CFR 68.130) as a Toxic with a 10000 lb Threshold Quantity
	SARA TITLE III:	Section 302 Extremely Hazardous Substances – Listed; 1000 lb Threshold Planning Quantity (40 CFR 355 Appendix A) Section 304 – Listed 10 lb Reportable Quantity (40 CFR 302.4) Section 311/312 Hazard Categories – Acute, Chronic, Fire, Reactive, Sudden Release (40 CFR 370.66) Section 313 Toxic Chemicals – Listed (40 CFR 372.65)
	TSCA:	On TSCA inventory.
	Other EPA	EPA list of Hazardous Air Contaminants: Listed EPA Organic Hazardous Air Pollutant (HAP) list (40 CFR 61.01): Listed EPA list of Pesticide Chemicals (40 CFR 180.151): Listed EPA NESHAPS (40 CFR 63.360) VOC Rule: 100% VOC
	FDA/USDA:	Not applicable.
	OSHA:	This product is hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. Ethylene Oxide Standard 29 CFR 1910.1047
	Other OSHA:	Listed under the Process Safety Management standard (29 CFR 1910.119) with 5000 lb Threshold Quantity.
US State:		California Proposition 65: Listed; cancer hazard; reproductive hazard California Director's List: Listed Florida Hazardous Substance List: Listed Massachusetts Extraordinarily Hazardous Substance List: Listed Minnesota Hazardous Substance List: Listed New Jersey Hazardous Substance List: Listed sn 0882 (Special Hazardous Substance; Environmental Hazardous Substance) Pennsylvania Right-to-know List: Listed
Canadian:	DSL:	Listed as Oxirane (published 5 April 1994)
	WHMIS:	Ingredient Disclosure List: Listed 0.1%, item 725 (1310) Classification: A; B1; D1A; D2A; D2B; F This MSDS complies with the Canadian Controlled Product Regulations.
EU:	CLP:	This product is not sold into the European Union.
	EINECS:	
	REACH:	
	Safety Data Sheets:	

16. OTHER INFORMATION INCLUDING INFORMATION ON PREPARATION AND REVISION		
Last Revision Date:	See top of each page under 'Effective Date'	
Reason for Issue:	Rev A supersedes Rev. 22 Jul 2009	Reformatted per OSHA GHS. Added part 10.1. Changed 11.4 Acute Ingestion LD50 from 72 to 330 mg/kg (no evidence located to support 72; web review, including IPCS. 2003. Ethylene Oxide. Geneva, World Health Organization, International Program on Chemical Safety. Concise International Chemical Assessment Document 54, p 1-57. http://www.inchem.org/documents/cicads/cicads/cicad54.htm .
Risk Phrases Used:	See Section 2.	
Hazard Ratings:	See Section 5.2	

SAFETY DATA SHEET

Effective Date: 1 April 2013	Revision: A	ARC	Language: EN
------------------------------	-------------	-----	--------------

THE FOLLOWING ABBREVIATIONS MAY BE USED IN THIS DOCUMENT:	
ACGIH	American Council of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
BOD 5, 10, 20	Biochemical Oxygen Demand, 5, 10 or 20 day
CAS	Chemical Abstract Service
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CLP	Classification, Labeling and Packaging
CNS	Central nervous system
CWA	Clean Water Act
D.O.T. or DOT	Department of Transportation
DSL	Domestic Substance List (Canada)
EC ₅₀	Effective concentration which induces a response halfway between the baseline and maximum.
EC	European Community
ECL	Existing Chemicals List (Korea)
EINECS	European Inventory of Existing Commercial Substances
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GHS	Globally Harmonized System
HAP	Hazardous Air Pollutant
HMIS	Hazardous Materials Information System
IARC	International Agency for Research on Cancer
IBC	International Bulk Chemical Code
IDL	Ingredient disclosure list
IDLH	Immediately Dangerous to Life and Health
IMO	International Maritime Organization
K _{St}	Deflagration Index
LC ₅₀	Median lethal concentration for 50% mortality of subject species by the inhalation route
LD ₅₀	Median lethal dose for 50% mortality of subject species by the oral or dermal route
LD _{Lo}	Median lethal dose low; the lowest dose of a substance introduced by any route other than inhalation reported to have caused death in humans or animals.
LEL / LFL	Lower Explosive Limit / Lower Flammable Limit
MARPOL	International Convention for the Prevention of Pollution from Ships
MSHA	Mine Safety Health Administration
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PBT	Persistent Bioaccumulative Toxic
PEL	Permissible Exposure Limit (default 8 hour day, 40 hour week TWA)
p/p	Parts per part
Ppm	Parts per million
p.s.i.g. or psig	Pounds per square inch (gauge pressure)
PSM	Process Safety Management
PVC	Polyvinyl chloride
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorization and Restriction of Chemical Substances
REL	Recommended Exposure Limit (default 10 hour day, 40 hour week TWA)
RMP	Risk Management Plan

- 3) **Where appropriate, advice regarding medical attention necessary for exposed individuals.** Since no one was injured or exposed during the release (without appropriate PPE), there was no need for medical attention.

We are in the process of completing the investigation for this EO release and will implement the necessary corrective actions to prevent it from happening again. If you need further information concerning this incident or report, please contact me at 630-928-1758 or khoffman@sterigenics.com.

Sincerely,



Kathleen Hoffman
Sr. Vice President – Global EH&S

Cc: Steve Ortiz – Santa Teresa General Manager.
Henry Jolly – NMDHSEM, Hazmat Coordinator

Submit Action Report

Spill Summary Report

NATIONAL RESPONSE CENTER 1-800-424-8802

GOVERNMENT USE ONLYGOVERNMENT USE ONLY***

Information released to a third party shall comply with any
applicable federal and/or state Freedom of Information and Privacy Laws

Incident Report # 1128845

INCIDENT DESCRIPTION

*Report taken by: MST3 ANNALIESE ENNIS at 17:35 on 18-SEP-15

Incident Type: FIXED

Incident Cause: OPERATOR ERROR

Affected Area:

Incident occurred on 14-SEP-15 at 07:47 local incident time.

Affected Medium: AIR ATMOSPHERE

REPORTING PARTY

Name: STEPHEN ORTIZ
Organization: STERIGENICS LLC

CHICAGO, IL

PRIMARY Phone: (575)5899300

Type of Organization: PRIVATE ENTERPRISE

SUSPECTED RESPONSIBLE PARTY

Name: STEPHEN ORTIZ
Organization: STERIGENICS LLC

CHICAGO, IL

PRIMARY Phone: (575)5899300

Type of Organization: PRIVATE ENTERPRISE

INCIDENT LOCATION

2400 AIRPORT RD County: DONA ANA

City: SANTA TERESA State: NM

RELEASED MATERIAL(S)

CHRIS Code: EPM Official Material Name: ETHYLENE OXIDE (30% OR LESS), PR
Also Known As:
Qty Released: 0 UNKNOWN AMOUNT

DESCRIPTION OF INCIDENT

CALLER IS REPORTING A RELEASE OF ETHYLENE OXIDE INTO THE ATMOSPHERE FROM A
STERILIZER AT THE FACILITY DUE TO OPERATOR ERROR.

INCIDENT DETAILS

Package: NO
Building ID:
Type of Fixed Object: OTHER
Power Generating Facility: NO
Generating Capacity:
Type of Fuel:
NPDES:
NPDES Compliance: UNKNOWN

IMPACT

Fire Involved: NO	Fire Extinguished: UNKNOWN		
INJURIES: NO	Hospitalized:	Empl/Crew:	Passenger:
FATALITIES: NO	Empl/Crew:	Passenger:	Occupant:



AI/AI/CO

110000-472341

RECEIVE

January 29, 2015

FEB - 3 2015

Director Air, Pesticides and Toxics
US EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

Air Toxics & Inspection
Coordination Branch
GEN-A

**RE: Notification of Compliance Status
Sterigenics' Santa Teresa, NM Facility**

Dear Sir:

This Notification of Compliance Status is being sent pursuant to 40 CFR 63.9(h) for Sterigenics' Santa Teresa, New Mexico facility. The facility is subject to the MACT emission standards in Section 63.362. On December 3, 2014 the facility's catalytic oxidizer system underwent performance testing. The results from that testing are contained herein.

Facility Name:

Sterigenics U.S., LLC – Santa Teresa Facility
2400 Airport Road
Santa Teresa, NM 88008

Method(s) Used to Determine Compliance - Section 63.9(h)(A)

Performance testing of the facility's catalytic oxidizer was conducted on December 3, 2014 in accordance with the test methods stated in 40 CFR 63.365 for Ethylene Oxide Sterilization Facilities.

Performance Test Results - Section 63.9(h)(B)

The catalytic oxidizer system (Donaldson abator) demonstrated an average efficiency of 99.60% for controlling ethylene oxide emissions from the Aeration Room and 99.67% efficiency for controlling ethylene oxide emissions from the back vents on Chambers 8, 9, 10, and 13, versus the 99.0% control standard in Section 63.362.

Methods to be Used for Determining Continued Compliance Section 63.9(h)(C)

The facility assures continued compliance with Section 63.362 standards by measuring / recording scrubber system pH and liquor tank level on a daily and weekly basis, respectively, and catalytic oxidizer bed temperature on a continuous basis.

Quantity of Ethylene Oxide Emitted During Reporting Period - Section 63.9(h)(D)

The Santa Teresa facility used approximately 1,010,601 pounds of ethylene oxide during all of 2014. Approximately 95% of that amount (960,071 pounds) is emitted from sterilization chamber vents (via vacuum pumps) to the Ceilcote wet scrubber system. Using the 99.954% control efficiency from the most recent Ceilcote system performance test conducted on December 12, 2012, calculated process emissions are approximately 442 pounds per year. Approximately 4% of the ethylene oxide (40,424 pounds) is vented from the facility's aeration rooms/cells and treated by the catalytic oxidizer emission control system. Using the 99.60% demonstrated control efficiency achieved during the December 3rd test, treated emissions from the aeration rooms total approximately 160 pounds annually. Prior to October 2013, backvent process emissions representing approximately 1% of the facility's total ethylene oxide usage (or 10,106 pounds), were not required to be controlled. The facility's NSR air permit issued June 2013 requires backvent emission on the facility's four largest chambers to be controlled. Using the 99.67% demonstrated control efficiency achieved during the December 3rd test on the four largest chambers,



calculated backvent emissions for 2014 totaled 4,655. In total, the facility's ethylene oxide emissions during 2014 were 5,257 pounds (2.6 tons).

Analysis Demonstrating Whether Source is a Major Source - Section 63.9(h)(E)

Based on the above emission analysis, the facility emits less than 10 tons/year of ethylene oxide and is an area source.

Description of Air Pollution Control Device & Control Efficiency for Facility's Emission Points - Section 63.9(h)(F)

A wet scrubber emission control device is used for controlling emissions from the facility's sterilization vents/vacuum pumps. The Ceilcote scrubber system demonstrated a control efficiency of 99.954% on December 12, 2012. Process emissions from the facility's aeration rooms/cells and 4 of the facility's thirteen sterilization chamber backvents are controlled by a catalytic oxidizer operating at a 99.60% and 99.67% performance efficiencies respectively. The facility's other chamber backvent emissions are not controlled.

Statement by Owner as to Whether the Facility Has Complied with the Relevant Standard - Section 63.9(h)(G)

To the best of our knowledge, the Santa Teresa facility has operated in compliance with the applicable standards in 40 CFR Part 63, Subpart O.

Certification Statement:

To the best of the undersigned's knowledge, information and belief formed after reasonable inquiry, the information submitted in this notification of the compliance status for Sterigenics' Santa Teresa, New Mexico facility is true, accurate, and complete.

KATHOFFMAN

Signature

Kathleen Hoffman

Printed Name

Senior Vice President - Global EHS

Title

29-Jun-2015

Date

If you should need further information, please contact Mrs. Laura Hartman at (630) 928-1724 or LHartman@Sterigenics.com.

Sincerely,

Laura Hartman
EHS Manager

Cc: Manager, Compliance and Enforcement Section - New Mexico AQB
Mr. Steve Ortiz - Santa Teresa General Manager

**REPORT OF
AIR POLLUTION SOURCE TESTING
OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO
ON DECEMBER 3, 2014**

Submitted to:

**NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
1301 Siler Road, Building B
Santa Fe, New Mexico 87507**

Submitted by:

**STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008**

NSR Permit No. 0733-M15

Prepared by:

**ECSi
PO Box 848
San Clemente, California 92674-0848**

Prepared on:

December 19, 2014

ECSi

CONTACT SUMMARY

CLIENT

Mr. Jeff Smith
Manager, Environmental Health and Safety
STERIGENICS U.S., LLC.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Phone: (847)263-3499
email: JPSmith@sterigenics.com

FACILITY

Mr. Steve Ortiz
General Manager
STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008

Phone: (575)589-9300
email: SOrtiz@sterigenics.com

PROPOSED TEST DATE

December 3, 2014

REGULATORY AGENCY

NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
1301 Siler Road, Building B
Santa Fe, New Mexico 87507

Phone: (505)476-4300
FAX: (505)476-4375
email: Stacktest.aqb@state.nm.us

TESTING CONTRACTOR

Daniel P. Kremer
Project Manager
ECSi, Inc.
PO Box 848
San Clemente, California 92674-0848

Phone: (949)400-9145
FAX: (949)281-2169
email: dankremer@ecsi1.com

ECSi

TABLE OF CONTENTS

	<u>PAGE NO.</u>
CONTACT SUMMARY	i
TABLE OF CONTENTS	ii
LIST OF TABLES	iii
LIST OF APPENDICES	iv
1.0 INTRODUCTION	1
2.0 EQUIPMENT	2
3.0 TESTING	3
4.0 RULE/COMPLIANCE REQUIREMENTS	4
5.0 TEST METHOD REFERENCE	5
5.1 Summary/Introduction	5
5.2 Volumetric Flow Measurement	5
5.3 EtO Mass-Emissions Measurement	6
5.4 Sample Transport	6
5.5 GC Injection	6
5.6 GC Conditions	7
5.7 Calibration Standards	7
5.8 Sampling Duration	8
5.9 Mass-Emissions Calculations	8
5.10 Leak Testing	8
6.0 TEST SCENARIO	9
7.0 QA/QC	10
7.1 Field Testing Quality Assurance	10
7.2 Calibration Procedures	10
8.0 TEST RESULTS	11
TABLES	12
APPENDICES	16

LIST OF TABLES

<u>TABLE</u>	<u>DESCRIPTION</u>	<u>PAGE NO.</u>
1	Ethylene Oxide Control Efficiency – Backvent	13
2	Ethylene Oxide Control Efficiency – Aeration	14
3	Ethylene Oxide Leak Testing	15

LIST OF APPENDICES

<u>APPENDIX</u>	<u>DESCRIPTION</u>	<u>PAGE NO.</u>
A	Calibration Data	A-1
B	Run #1 Chromatograms – Backvent	B-1
C	Run #1 Chromatograms – Aeration	C-1
D	Run #2 Chromatograms – Aeration	D-1
E	Run #3 Chromatograms – Aeration	E-1
F	Field Data and Calculation Worksheets	F-1
G	Calibration Gas Certificates	G-1

1.0 INTRODUCTION

On Wednesday, December 3, 2014, ECSi performed air pollution source testing of an ethylene oxide (EtO) emission-control system operated by Sterigenics U.S., LLC. in Santa Teresa, New Mexico. The control device tested was a Donaldson Abator catalytic oxidizer, which is currently used to control emissions from two aeration rooms, three aeration cells, and four sterilization chamber backvents. The purpose of the testing program was to evaluate continued compliance with EPA requirements under the current National Emissions Standards for Hazardous Air Pollutants (NESHAP), Subpart O - Ethylene Oxide Sterilization Facilities, and with requirements in the facility's NSR Permit No. 0733-M15 issued by the New Mexico Environment Department (NMED).

2.0 EQUIPMENT

The EtO gas-sterilization system is comprised of thirteen commercial sterilizers, all discharging through dry screw or liquid-ring vacuum pumps to a packed-tower Ceilcote acid scrubber emission control device. Two aeration rooms, three aeration cells and four sterilization chamber backvents are all discharged to a Donaldson Abator catalytic oxidizer emission-control device. The gas-sterilization and emission-control equipment consists of the following:

- Thirteen Gas Sterilizers, each comprised of a steam-heated sterilization chamber (varying in size from 13-30 pallet capacity), a dry screw or liquid ring recirculating vacuum pump chamber evacuation system ("chamber vacuum vent"), and a backdraft valve ("chamber backvent");
- Two aeration rooms and three aeration cells, each comprised of a heated aeration chamber and a chamber exhaust system.

Sterilizer vacuum pump emissions are controlled by:

- One packed-tower Ceilcote chemical scrubber, equipped with a packed reaction/interface column, a scrubber fluid recirculation system, a scrubber fluid reaction/storage tank, and a dedicated blower exhaust system.

Aeration room/aeration cells and sterilizer backvent (Sterilizers 8, 9, 10 and 13) emissions are controlled by:

- One Donaldson EtO Abator catalytic oxidizer, 20,000 SCFM, equipped with a prefilter, a gas-fired heater, an exhaust gas heat exchanger, a reactive catalyst bed, and an exhaust blower.

3.0 TESTING

EtO source testing was conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365(d) and Method 18 in 40 CFR Part 60, Appendix A. EtO emissions monitoring for each test run was conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process. A total of three one-hour aeration test runs were performed. Testing of the backvent process consisted of a 15-minute test run.

During backvent and aeration testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer were determined using direct source sample injection into the gas chromatograph (GC). All backvent and aeration testing was performed using freshly sterilized product. The testing program was conducted in accordance with the procedures outlined in the following sections.

4.0 RULE/COMPLIANCE REQUIREMENTS

The facility's Donaldson Abator catalytic oxidizer system was tested to determine compliance with the current federal EPA National Emissions Standards for Hazardous Air Pollutants (NESHAP) in 40 CFR Part 63, Subpart O and the facility's NSR permit. Applicable provisions in the NESHAP standard include Sections 63.362(d) and 63.363(b)(4)(i). Specifically, the current testing was performed to demonstrate continued compliance with the following requirements:

- The emissions from the aeration process must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight. {Section 63.362(d)}
- The emissions from the backvents of Sterilizers 8, 9, 10, and 13 must be discharged to the catalytic oxidizer, CD-3, with an EtO emission-reduction efficiency of at least 99.0%. {NSR Permit Section A803 A.}

Testing is required to demonstrate compliance with these requirements. Source testing of the emission-control device is required annually, in accordance with Federal EPA and NMED requirements.

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

The testing procedures outlined herein are based on USEPA source-sampling methods. EtO control efficiency and mass-emissions testing for the aeration process was conducted following USEPA CFR40, Part 63.365(d) requirements. EtO emissions monitoring for each test run was conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour test interval of the 24-hour aeration process. A total of three (3) - one-hour test runs were performed of the aeration process.

EPA's Subpart O standards currently do not regulate backvent emissions from ethylene oxide sterilization facilities. However the testing procedures in Part 63.365(d) are equally suitable for testing backvent process emissions and were used for this testing, except the sampling duration was limited by the duration of the backvent emissions cycle, which is approximately 15 minutes. One 15-minute test run of the backvent process is included in the test results.

During backvent and aeration testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer were determined using direct source sample injection into the gas chromatograph (GC). All backvent and aeration testing was performed using freshly sterilized product.

Operation and documentation of process conditions were performed by personnel from Sterigenics using existing monitoring instruments installed by the manufacturer on the equipment to be tested. In accordance with the procedures established in USEPA CFR40, Part 63, Subpart O, Section 63.363(b)(3), the following parameter was recorded: catalyst bed operating temperature. Process condition data is recorded in Tables 1 and 2.

5.2 VOLUMETRIC FLOW MEASUREMENT

Exhaust gas flow at the outlet of the catalytic oxidizer was determined by EPA Method 2C using a standard pitot tube and an inclined-oil manometer. Sampling ports were installed in accordance with EPA Method 1, and were located far enough from any flow disturbances to permit accurate flow measurement.

Temperature measurements were obtained from a type K thermocouple and thermometer attached to the sampling probe. Exhaust gas composition was assumed to be air and small amounts of water vapor. Water vapor was negligible, at about 3 percent.

5.3 CONTROL EFFICIENCY AND MASS EMISSIONS MEASUREMENT

During backvent and aeration testing, EtO emissions at the inlet and outlet of the catalytic oxidizer were determined using direct source sample injection into the GC. The mass of EtO emitted to the inlet and from the outlet was determined using the equation shown below in Section 5.9. Mass-mass control-efficiency of EtO during aeration was calculated by comparing the mass of EtO vented to the system inlet to the mass of EtO vented from the system outlet.

During backvent and aeration testing, vented gas was analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) was used to quantify inlet EtO emissions, and a photoionization detector (PID) was used to quantify low-level EtO emissions at the emission-control device outlet.

5.4 SAMPLE TRANSPORT

Source gas was pumped to the GC at approximately 1000 cubic centimeters per minute (cc/min) from the sampling ports through two lengths of Teflon® sample line, each with a nominal volume of approximately 75 cubic centimeters (cc) and an outer diameter of 0.25 inch. At the inlet, the sampling port was located in the aeration discharge duct, upstream of the oxidizer. At the outlet of the catalytic oxidizer, sampling ports were located in the exhaust stack downstream of the catalyst bed.

5.5 GC INJECTION

Source-gas samples were then injected into the GC which was equipped with two heated sampling loops, each containing a volume of approximately 2cc and maintained at 100 degrees Celsius (C). Injections occurred at approximately one-minute intervals during backvent testing, and at approximately five-minute intervals during aeration testing. Helium was the carrier gas for both the FID and PID.

5.6 GC CONDITIONS

The packed columns for the GC were both operated at 80 degrees C. The columns were stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

During the analysis, the FID was operated at 250 degrees C. The support gases for the FID were helium (99.999% pure), hydrogen (99.995% pure) and air (99.9999% pure). Any unused sample gas was vented from the GC system back to the inlet of the control device being tested.

5.7 CALIBRATION STANDARDS

The FID was calibrated for mid-range part-per-million-by-volume (ppmv) level analysis using gas proportions similar to the following:

- 1) 1,000 ppmv EtO, balance nitrogen
- 2) 100 ppmv EtO, balance nitrogen
- 3) 50 ppmv EtO, balance nitrogen (audit gas)
- 4) 10 ppmv EtO, balance nitrogen
- 5) 1 ppmv EtO, balance nitrogen

The PID was calibrated for low-range ppmv level analyses using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

Each of these calibration standards was in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates are attached as Appendix G.

5.8 SAMPLING DURATION

Backvent testing consisted of a one 15-minute test run, which encompassed the entire duration of a single cycle of the backvent process. Since aeration is a 24-hour process at this facility, with constant discharge flow from the aeration chambers to the Donaldson Abator emission-control system, aeration testing

consisted of three (3), 1-hour test runs. Each test run was performed with freshly sterilized product in the sterilization chambers and/or aeration rooms.

5.9 CONTROL-EFFICIENCY/MASS-EMISSIONS CALCULATIONS

Mass emissions of EtO during backvent and aeration were calculated using the following equation:

$$\text{MassRate} = (\text{VolFlow})(\text{MolWt})(\text{ppmv EtO}/10^6)/(\text{MolVol})$$

Where:

MassRate = EtO mass flow rate, pounds per minute

VolFlow = Corrected volumetric flow rate, standard cubic feet per minute at 68 degrees F

MolWt = 44.05 pounds EtO per pound mole

ppmv EtO = EtO concentration, parts per million by volume

10^6 = Conversion factor, ppmv per "cubic foot per cubic foot"

MolVol = 385.32 cubic feet per pound mole at one atmosphere and 68 degrees F

Mass-mass control efficiency of EtO was calculated for backvent and aeration. Results of the control-efficiency testing are presented in Table 1.

5.10 LEAK TESTING

Testing for EtO leaks was conducted during the exposure and chamber evacuation phases of the sterilization and exhaust cycles of the sterilizer. These conditions represent maximum sterilant gas mass flow through the system.

EtO leak testing was performed using a Bacharach EO Leakator, Part Number 19-7057, Gas Leak Detector, equipped with a metal-oxide semi-conductor sensor, an audible signal, and a visual display. The lower detection limit of the instrument is less than the leak definition specified for EtO. This leak definition is 10 ppm EtO for sterilant gas composed of 100 percent EtO.

EtO concentration was measured one centimeter from the surface of all accessible components of the sterilizer and emission-control device that are potential sources of EtO leakage. Each component found to be leaking was identified and tagged. The date and the results of the EtO measurement for each leaking component were entered on that component's tag. The leak test data is summarized in Section 8.0 and in Table 2.

6.0 TEST SCENARIO

Backvent and aeration testing was performed during normal process load conditions. One backvent test run and three aeration test runs were conducted in series to verify the performance of the emission-control device. The testing schedule was as follows:

- 1) Testing equipment was set up and calibrated.
- 2) Backvent Test Run #1 was conducted with freshly sterilized product in sterilization chamber. Sampling was performed at the inlet and the outlet of the catalytic oxidizer.
- 3) Aeration Test Run #1 was conducted with freshly sterilized product in aeration. Sampling was performed at the inlet and the outlet of the catalytic oxidizer.
- 4) Aeration Test Run #2 was conducted with freshly sterilized product in aeration. Sampling was performed at the inlet and the outlet of the catalytic oxidizer.
- 5) Aeration Test Run #3 was conducted with freshly sterilized product in aeration. Sampling was performed at the inlet and the outlet of the catalytic oxidizer.
- 6) Post calibration check was performed, testing equipment was packed.

7.0 QA/QC

7.1 FIELD TESTING QUALITY ASSURANCE

At the beginning of the test, the sampling system was leak checked at a vacuum of 15 inches of mercury. The sampling system was considered leak free when the flow indicated by the rotameters fell to zero.

At the beginning of the test, a system blank was analyzed to ensure that the sampling system was free of EtO. Ambient air was introduced at the end of the heated sampling line and drawn through the sampling system line to the GC for analysis. The resulting chromatogram also provided a background level for non-EtO components (i.e. ambient air, carbon dioxide, water vapor) which are present in the source gas stream due to the ambient dilution air which is drawn into the emission-control device, and due to the destruction of EtO by the emission-control device which produces carbon dioxide and water vapor. This chromatogram, designated AMB, is included with the calibration data in Appendix A.

7.2 CALIBRATION PROCEDURES

The GC system was calibrated at the beginning and conclusion of each day's testing. Using the Peaksimple II analytical software, a point-to-point calibration curve was constructed for each detector. A gas cylinder of similar composition as the calibration gases, but certified by a separate supplier, was used to verify calibration gas composition and GC performance.

All calibration gases and support gases used were of the highest purity and quality available. A copy of the laboratory certification for each calibration gas is attached as Appendix G.

8.0 TEST RESULTS

The catalytic oxidizer was found to have an average EtO control efficiency of 99.67% for the backvent process, and 99.60% for the aeration process. During backvent and aeration testing the catalytic oxidizer was operated at 280 degrees F (i.e., bed outlet temperature). In accordance with state and federal requirements, backvent and aeration discharge streams must be vented to control equipment with an EtO emission-reduction efficiency of at least 99 percent by weight. The facility's Donaldson Abator catalytic oxidizer met this requirement. All thirteen sterilizers were also tested for EtO leaks and found to be leak free.

The test results are summarized in Tables 1, 2 and 3. These tables include results for EtO control efficiency of the emission-control device, and for the leak testing of the sterilizers. Chromatograms and chromatographic supporting data are attached as Appendices A through E. Copies of field data and calculation worksheets are attached as Appendix F.

TABLES

TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY - BACKVENT
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO
ON DECEMBER 3, 2014

<u>CYCLE</u> <u>PHASE</u>	<u>INJECTION</u> <u>TIME</u>	<u>INLET ETO</u> <u>CONC. (PPM)(1)</u>	<u>OUTLET ETO</u> <u>CONC. (PPM)(2)</u>	<u>ETO CONTROL</u> <u>EFFICIENCY</u>
Backvent(3)	848	218	0.83	99.6193
Backvent	849	89.7	0.52	99.4203
Backvent	850	55.3	0.19	99.6564
Backvent	851	50.2	0.20	99.6016
Backvent	853	48.7	0.10	99.7947
Backvent	854	47.6	0.30	99.3697
Backvent	855	46.9	0.03	99.9360
Backvent	856	46.2	0.11	99.7619
Backvent	858	45.9	0.06	99.8693
Backvent	859	45.9	0.10	99.7821
Backvent	900	45.5	0.22	99.5165
Backvent	901	45.9	0.13	99.7168
Backvent	902	<u>45.5</u>	<u>0.16</u>	<u>99.6484</u>
TIME-WEIGHTED AVERAGE:		63.9	0.2269	99.6687
NMED REQUIRED CONTROL EFFICIENCY:				99%

Notes:

- (1) - PPM = parts per million by volume
- (2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
- (3) - The backvent phase test run started at 8:47, ended at 9:02.
- (4) - The average catalyst bed temperature recorded during the test run was 280 degrees F.

ECSi

TABLE 2
ETHYLENE OXIDE CONTROL EFFICIENCY - AERATION
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO
ON DECEMBER 3, 2014

<u>RUN NUMBER</u>	<u>INJECTION TIME</u>	<u>INLET ETO CONC. (PPM)(1)</u>	<u>OUTLET ETO CONC. (PPM)(2)</u>	<u>ETO CONTROL EFFICIENCY</u>
1(3)	908	44.5	0.26	99.4157
1	913	43.7	0.13	99.7025
1	918	43.1	0.13	99.6984
1	923	42.5	0.19	99.5529
1	928	42.9	0.27	99.3706
1	933	43.7	0.12	99.7254
1	938	40.9	0.28	99.3154
1	943	42.5	0.21	99.5059
1	948	43.4	0.20	99.5392
1	953	44.6	0.24	99.4619
1	958	45.6	0.21	99.5395
1	1003	46.8	0.14	99.7009
2(4)	1008	47.3	0.15	99.6829
2	1013	47.2	0.24	99.4915
2	1018	46.3	0.18	99.6112
2	1023	46.4	0.16	99.6552
2	1028	51.8	0.17	99.6718
2	1033	51.8	0.20	99.6139
2	1038	52.2	0.23	99.5594
2	1043	51.5	0.19	99.6311
2	1048	52.3	0.20	99.6176
2	1053	53.3	0.19	99.6435
2	1058	53.5	0.13	99.7570
2	1103	53.9	0.17	99.6846
3(5)	1108	54.5	0.12	99.7798
3	1113	53.2	0.22	99.5865
3	1118	53.6	0.20	99.6269
3	1123	53.8	0.16	99.7026
3	1128	53.8	0.27	99.4981
3	1133	54.0	0.25	99.5370
3	1138	53.2	0.22	99.5865
3	1143	53.2	0.24	99.5489
3	1148	53.2	0.14	99.7368
3	1153	52.1	0.25	99.5202
3	1158	51.6	0.18	99.6512
3	1203	<u>52.7</u>	<u>0.11</u>	<u>99.7913</u>
TIME-WEIGHTED AVERAGE:		49.18	0.1931	99.6032
NMED REQUIRED CONTROL EFFICIENCY:				99%

Notes:

- (1) - PPM = parts per million by volume
- (2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
- (3) - Aeration Phase Test Run #1 started at 9:05, ended at 10:05.
- (4) - Aeration Phase Test Run #2 started at 10:05, ended at 11:05.
- (5) - Aeration Phase Test Run #3 started at 11:05, ended at 12:05.
- (6) - During aeration testing, the average recorded catalyst bed temperature was 280 deg F

ECSI



870002 11 0000 7254/

RECEIVED
US EPA, DALLAS, TX
ASSOCIATE DIRECTOR

February 10, 2016

16 FEB 12 AM 10:47

Director Air, Pesticides and Toxics
US EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

COMPLIANCE ASSURANCE
& ENFORCEMENT DIV.

RE: Notification of Compliance Status
Sterigenics' Santa Teresa, NM Facility

A1/A1/CO

Dear Sir:

This Notification of Compliance Status is being sent pursuant to 40 CFR 63.9(h) for Sterigenics' Santa Teresa, New Mexico facility. The facility is subject to the MACT emission standards in Section 63.362. On December 18, 2015 the facility's catalytic oxidizer system underwent performance testing. The results from that testing are contained herein.

Facility Name:

Sterigenics U.S., LLC – Santa Teresa Facility
2400 Airport Road
Santa Teresa, NM 88008

Method(s) Used to Determine Compliance - Section 63.9(h)(A)

Performance testing of the facility's catalytic oxidizer was conducted on December 18, 2015 in accordance with the test methods stated in 40 CFR 63.365 for Ethylene Oxide Sterilization Facilities.

Performance Test Results - Section 63.9(h)(B)

The catalytic oxidizer system (Donaldson abator) demonstrated an average control efficiency of 99.978% for ethylene oxide emissions from both the Aeration Room and the back vents, versus the 99.0% control standard in Section 63.362.

Methods to be Used for Determining Continued Compliance Section 63.9(h)(C)

The facility assures continued compliance with Section 63.362 standards by measuring / recording scrubber system pH and liquor tank level on a daily and weekly basis, respectively, and catalytic oxidizer bed temperature on a continuous basis.

Quantity of Ethylene Oxide Emitted During Reporting Period - Section 63.9(h)(D)

The Santa Teresa facility controlled approximately 1,008,639 pounds of ethylene oxide during all of 2015. Approximately 95% of that amount (958,207 pounds) is emitted from sterilization chamber vents (via vacuum pumps) to the Ceilcote wet scrubber system. Using the 99.954% control efficiency from the most recent Ceilcote system performance test conducted on December 12, 2012, calculated process emissions are approximately 441 pounds per year. Approximately 4% of the ethylene oxide (40,346 pounds) is vented from the facility's aeration rooms/cells and treated by the catalytic oxidizer emission control system. Using the 99.978% demonstrated control efficiency achieved during the December 18th test, treated emissions from the aeration rooms total approximately 9 pounds annually. Backvent process emissions represent approximately 1% of the facility's total ethylene oxide usage (or 10,086 pounds). Prior to 2015, the backvent process emissions from 4 of the 13 chambers were controlled by the catalytic oxidizer. The facility's NSR air permit issued in December 2014 required backvent emissions on all of the facility's chambers to be routed to the catalytic oxidizer. Routing the remaining backvents was completed on January 11, 2105. Using the 99.978% demonstrated control efficiency achieved during the



December 18th test on the 4 backvents prior to January 11 and all backvents after January 11, calculated backvent emissions for 2015 totaled 17 pounds. In total, the facility had an estimated 467 pounds (0.2 tons) of ethylene oxide point source emissions during 2015.

Analysis Demonstrating Whether Source is a Major Source - Section 63.9(h)(E)

Based on the above emission analysis, the facility emits less than 10 tons/year of ethylene oxide and is an area source.

Description of Air Pollution Control Device & Control Efficiency for Facility's Emission Points - Section 63.9(h)(F)

A wet scrubber emission control device is used for controlling emissions from the facility's sterilization vents/vacuum pumps. The Ceilcote scrubber system demonstrated a control efficiency of 99.954% on December 12, 2012. Process emissions from the facility's aeration rooms/cells and the facility's thirteen sterilization chamber backvents are controlled by a catalytic oxidizer operating at a 99.978% performance efficiency.

Statement by Owner as to Whether the Facility Has Complied with the Relevant Standard - Section 63.9(h)(G)

To the best of our knowledge, the Santa Teresa facility has operated in compliance with the applicable standards in 40 CFR Part 63, Subpart O.

Certification Statement:

To the best of the undersigned's knowledge, information and belief formed after reasonable inquiry, the information submitted in this notification of the compliance status for Sterigenics' Santa Teresa, New Mexico facility is true, accurate, and complete.

Kathleen Hoffman
Signature

Kathleen Hoffman
Printed Name

Senior Vice President - Global EHS
Title

11 - Feb - 2015
Date

If you should need further information, please contact Mrs. Laura Hartman at (630) 928-1724 or LHartman@Sterigenics.com.

Sincerely,

Laura Hartman
Laura Hartman
EHS Manager

Cc: Manager, Compliance and Enforcement Section - New Mexico AQB
Mr. Steve Ortiz - Santa Teresa General Manager



**New Mexico Environment Department
Air Quality Bureau
Compliance and Enforcement Section
525 Camino de los Marquez, Suite 1
Santa Fe, NM 87505
Phone (505) 476-4300 Fax (505) 476-4375**



Version 05.02.13

NMED USE ONLY	
TEMPO	

REPORTING SUBMITTAL FORM

NMED USE ONLY	
Staff	
Admin	

PLEASE NOTE: ® - Indicates required field

SECTION I - GENERAL COMPANY AND FACILITY INFORMATION					
A. ® Company Name: Sterigenics U.S. LLC			D. ® Facility Name: Santa Teresa Facility		
B.1 ® Company Address: 2015 Spring Road, Ste 650			E.1 ® Facility Address: 2400 Airport Road		
B.2 ® City: Oak Brook	B.3 ® State: IL	B.4 ® Zip: 60523	E.2 ® City: Santa Teresa	E.3 ® State: NM	E.4 ® Zip: 88008
C.1 ® Company Environmental Contact: Laura Hartman	C.2 ® Title: EHS Manager		F.1 ® Facility Contact: Steve Ortiz	F.2 ® Title: General Manager	
C.3 ® Phone Number: 630-928-1724	C.4 ® Fax Number: 847-855-6123		F.3 ® Phone Number: 575-589-9300	F.4 ® Fax Number: 575-589-9729	
C.5 ® Email Address: LHartman@Sterigenics.com			F.5 ® Email Address: SOrtiz@Sterigenics.com		
G. Responsible Official: (Title V only):		H. Title:	I. Phone Number:		J. Fax Number:
K. ® AI Number: 127-PRN2014001	L. Title V Permit Number:	M. Title V Permit Issue Date:	N. NSR Permit Number: 0733-M15-R1		O. NSR Permit Issue Date: 12/23/2014
P. Reporting Period: From: January 1, 2015 To: December 31, 2015					

SECTION II - TYPE OF SUBMITTAL (check one that applies)				
A. <input type="checkbox"/>	Title V Annual Compliance Certification	Permit Condition(s):	Description:	
B. <input type="checkbox"/>	Title V Semi-annual Monitoring Report	Permit Condition(s):	Description:	
C. <input type="checkbox"/>	NSPS Requirement (40CFR60)	Regulation:	Section(s):	Description:
D. <input checked="" type="checkbox"/>	MACT Requirement (40CFR63)	Regulation: Subpart A	Section(s): 63.9(h)	Description: Notification of Compliance Status Report
E. <input type="checkbox"/>	NMAC Requirement (20.2.xx) or NESHAP Requirement (40CFR61)	Regulation:	Section(s):	Description:
F. <input type="checkbox"/>	Permit or Notice of Intent (NOI) Requirement	Permit No. <input type="checkbox"/> or NOI No. <input type="checkbox"/>	Condition(s):	Description:
G. <input type="checkbox"/>	Requirement of an Enforcement Action	NOV No. <input type="checkbox"/> or SFO No. <input type="checkbox"/> or CD No. <input type="checkbox"/> or Other <input type="checkbox"/>	Section(s):	Description:

SECTION IV - CERTIFICATION			
After reasonable inquiry, I <u>Kathleen Hoffman</u> certify that the information in this submittal is true, accurate and complete. (name of reporting official)			
® Signature of Reporting Official: <u>Kathleen Hoffman</u>		® Title: SR. VP - Global EHS	® Date: 2/10/2016
		® Responsible Official for Title V? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Reviewed By: _____

Date Reviewed: _____

ED_005212_00004260-00074



HI/AI/CO

11 0000472541

RECEIVE

JAN 24 2014

Air/Toxics & Inspection
Coordination Branch
6EN-A

January 22, 2014

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: **Summary Report -Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: July 1, 2013 - December 31, 2013**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: July 1, 2013
Ending: December 31, 2013

(D) Description of Process Units
The facility employs 13 ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and four chamber backvents are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00075



AI/AI/CO

110000472541

NS41 vol 6
RECEIVE

JUL 23 2014

July 21, 2014

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

Air/Toxics & Inspection
Coordination Branch
SEN-A

RE: **Summary Report –Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: January 1, 2014 – June 30, 2014**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: January 1, 2014
Ending: June 30, 2014

(D) Description of Process Units
The facility employs 13 ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and four chamber backvents are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00076



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart recorder	Truline DR450T	8939760945047

(G) Date of Latest CMS Certification or Audit
June 28, 2014

(H) Total Operating Time of Affected Source during Reporting Period
4212.5 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

There were no emission system CMS instrumentation outages during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period

There have been no changes to the CMS, process or controls since the last reporting period.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

KATHOFFMAN

Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report

July 21, 2014

If you have any questions regarding this report, please contact Jeffrey Smith at either (847) 263-3499 or JPSmith@Sterigenics.com.

Sincerely,

Kevin Wagner
Director EHS

Cc: Manager, Compliance and Enforcement Section – New Mexico AQB
Mr. Steve Ortiz – Santa Teresa General Manager

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com



New Mexico Environment Department
Air Quality Bureau
Compliance and Enforcement Section
1301 Siler Road Building B
Santa Fe, NM 87507
Phone (505) 476-4300 Fax (505) 476-4375



Version 07.03.08

NMED USE ONLY	
DTS	
TEMPO	

REPORTING SUBMITTAL FORM

NMED USE ONLY	
Staff	
Admin	

PLEASE NOTE: ® - Indicates required field

SECTION I - GENERAL COMPANY AND FACILITY INFORMATION					
A. ® Company Name: Sterigenics U.S., LLC			D. ® Facility Name: Santa Teresa Facility		
B.1 ® Company Address: 2015 Spring Rd., Ste 650			E.1 ® Facility Address: 2400 Airport Road		
B.2 ® City: Oak Brook	B.3 ® State: IL	B.4 ® Zip: 60523 ¹	E.2 ® City: Santa Teresa	E.3 ® State: NM	E.4 ® Zip: 88008
C.1 ® Company Environmental Contact: Jeffrey Smith		C.2 ® Title: EHS Manager	F.1 ® Facility Contact: Steve Ortiz		F.2 ® Title: General Manager
C.3 ® Phone Number: 847/263-3499		C.4 ® Fax Number: 847/855-6123	F.3 ® Phone Number: 575/589-9300		F.4 ® Fax Number: FORMTEXT 575/589-9729
C.5 ® Email Address: JPSmith@Sterigenics.com			F.5 ® Email Address: SOrtiz@Sterigenics.com		
G. Responsible Official: (Title V only):		H. Title:		I. Phone Number:	
				J. Fax Number:	
K. ® AI Number: 127-PRN20090001	L. Title V Permit Number:		M. Title V Permit Issue Date:		N. NSR Permit Number: NPR-0733M-15
O. NSR Permit Issue Date:					
P. Reporting Period: From: 1/1/2014 To: 6/30/2014		OR	Q. Proposed Test Date:		OR
			R. Actual Test Date:		

SECTION II - TYPE OF SUBMITTAL (check one that applies)				
A. <input type="checkbox"/>	Title V Annual Compliance Certification	Permit Condition(s):	Description:	
B. <input type="checkbox"/>	Title V Semi-annual Monitoring Report	Permit Condition(s):	Description:	
C. <input type="checkbox"/>	NSPS Requirement (40CFR60)	Regulation:	Section(s):	Description:
D. <input checked="" type="checkbox"/>	MACT Requirement (40CFR63)	Regulation: Subpart A	Section(s): 63.10(e)(3)	Description: Summary Report-Gaseous and Opacity Excess Emission
E. <input type="checkbox"/>	NMAC Requirement (20.2.xx) or NESHAP Requirement (40CFR61)	Regulation:	Section(s):	Description:
F. <input type="checkbox"/>	Permit or Notice of Intent (NOI) Requirement	Permit No. <input type="checkbox"/> or NOI No. <input type="checkbox"/>	Condition(s):	Description:
G. <input type="checkbox"/>	Requirement of an Enforcement Action	NOV No. <input type="checkbox"/> or SFO No. <input type="checkbox"/> or CD No. <input type="checkbox"/> or Other <input type="checkbox"/>	Section(s):	Description:

SECTION III - PERIODIC EMISSIONS TEST NOTIFICATIONS, TEST PROTOCOLS AND TEST REPORTS (if applicable)					
T. <input type="checkbox"/>	A. Test Report <input type="checkbox"/> CMT: _____		B. Test Protocol <input type="checkbox"/>		Description: (Emission Units to be Tested)
	D. Test (EPA Methods) <input type="checkbox"/>		E. Test (EPA Methods) <input type="checkbox"/>		
	F. RATA Test <input type="checkbox"/>		G. Opacity Test <input type="checkbox"/>		H. Portable Analyzer (Periodic Test) <input type="checkbox"/>

SECTION IV - CERTIFICATION			
After reasonable inquiry, I <u>Kathleen Hoffman</u> certify that the information in this submittal is true, accurate and complete. (name of reporting official)			
® Signature of Reporting Official: <u>Kathleen Hoffman</u>		® Title: SR. VP -Global EHS	® Date: 7/21/14
		® Responsible Official for Title V? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Reviewed By: _____

Date Reviewed: _____

ED_005212_00004260-00078



11 0000472541

RECEIVED
US EPA, DALLAS, TX
ASSOCIATE DIRECTOR

A1/A1/CO

16 FEB -1 PM 3:39

COMPLIANCE ASSURANCE
& ENFORCEMENT DIV.

110000472541

NM V.8

January 27, 2016

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: Summary Report -Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: July 1, 2015 - December 31, 2015
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The Santa Teresa facility encountered breakdowns of the catalytic oxidizer totaling less than 3 hours, but the breakdowns of the control equipment did not result in uncontrolled emissions being emitted to the atmosphere.

The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide
- (C) Reporting Period Dates
Beginning: July 1, 2015
Ending: December 31, 2015
- (D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and chamber backvents are treated in a catalytic oxidizer system.
- (E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
--------------	-------------------	-----------------------



New Mexico Environment Department
Air Quality Bureau
Compliance and Enforcement Section
525 Camino de los Marquez, Suite 1
Santa Fe, NM 87505
Phone (505) 476-4300 Fax (505) 476-4375



Version 05.02.13

NMED USE ONLY	
TEMPO	

REPORTING SUBMITTAL FORM

NMED USE ONLY	
Staff	
Admin	

PLEASE NOTE: ® - Indicates required field

SECTION I - GENERAL COMPANY AND FACILITY INFORMATION					
A. ® Company Name: Sterigenics U.S. LLC			D. ® Facility Name: Santa Teresa Facility		
B.1 ® Company Address: 2015 Spring Road, Ste 650			E.1 ® Facility Address: 2400 Airport Road		
B.2 ® City: Oak Brook	B.3 ® State: IL	B.4 ® Zip: 60523 ¹	E.2 ® City: Santa Teresa	E.3 ® State: NM	E.4 ® Zip: 88008
C.1 ® Company Environmental Contact: Laura Hartman		C.2 ® Title: EHS Manager	F.1 ® Facility Contact: Steve Ortiz		F.2 ® Title: General Manager
C.3 ® Phone Number: 630-928-1724		C.4 ® Fax Number: 847-855-6123	F.3 ® Phone Number: 575-589-9300		F.4 ® Fax Number: 575-589-9729
C.5 ® Email Address: LHartman@Sterigenics.com			F.5 ® Email Address: SOrtiz@Sterigenics.com		
G. Responsible Official: (Title V only):		H. Title:	I. Phone Number:		J. Fax Number:
K. ® AI Number: 127-PRN2014001	L. Title V Permit Number:	M. Title V Permit Issue Date:	N. NSR Permit Number: 0733-M15-R1		O. NSR Permit Issue Date: 12/23/2014
P. Reporting Period: From: July 1, 2015 To: December 31, 2015					

SECTION II - TYPE OF SUBMITTAL (check one that applies)				
A. <input type="checkbox"/>	Title V Annual Compliance Certification	Permit Condition(s):	Description:	
B. <input type="checkbox"/>	Title V Semi-annual Monitoring Report	Permit Condition(s):	Description:	
C. <input type="checkbox"/>	NSPS Requirement (40CFR60)	Regulation:	Section(s):	Description:
D. <input checked="" type="checkbox"/>	MACT Requirement (40CFR63)	Regulation: Subpart A	Section(s): 63.10(e)(3)	Description: Summary Report-Gaseous and Opacity Excess Emission
E. <input type="checkbox"/>	NMAC Requirement (20.2.xx) or NESHAP Requirement (40CFR61)	Regulation:	Section(s):	Description:
F. <input type="checkbox"/>	Permit or Notice of Intent (NOI) Requirement	Permit No. <input type="checkbox"/> : or NOI No. <input type="checkbox"/> :	Condition(s):	Description:
G. <input type="checkbox"/>	Requirement of an Enforcement Action	NOV No. <input type="checkbox"/> : or SFO No. <input type="checkbox"/> : or CD No. <input type="checkbox"/> : or Other <input type="checkbox"/> :	Section(s):	Description:

SECTION IV - CERTIFICATION			
After reasonable inquiry, I <u>Kathleen Hoffman</u> certify that the information in this submittal is true, accurate and complete. (name of reporting official)			
® Signature of Reporting Official: <u>Kathleen Hoffman</u>		® Title: SR, VP - Global EHS	® Date: 1/27/2016
		® Responsible Official for Title V? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Reviewed By: _____

Date Reviewed: _____

ED_005212_00004260-00080



AI/AI/CO 110000472541
NS41 vol 6
RECEIVE

July 21, 2014

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

JUL 23 2014
Air/Toxics & Inspection
Coordination Branch
SEN-A

RE: **Summary Report –Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: January 1, 2014 – June 30, 2014**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: January 1, 2014
Ending: June 30, 2014

(D) Description of Process Units
The facility employs 13 ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and four chamber backvents are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00081



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart recorder	Truline DR450T	8939760945047

(G) Date of Latest CMS Certification or Audit
June 28, 2014

(H) Total Operating Time of Affected Source during Reporting Period
4212.5 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

There were no emission system CMS instrumentation outages during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period

There have been no changes to the CMS, process or controls since the last reporting period.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

KATHOFFMAN

Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report

July 21, 2014

If you have any questions regarding this report, please contact Jeffrey Smith at either (847) 263-3499 or JPSmith@Sterigenics.com.

Sincerely,

Kevin Wagner
Director EHS

Cc: Manager, Compliance and Enforcement Section – New Mexico AQB
Mr. Steve Ortiz – Santa Teresa General Manager

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com



New Mexico Environment Department
Air Quality Bureau
Compliance and Enforcement Section
1301 Siler Road Building B
Santa Fe, NM 87507
Phone (505) 476-4300 Fax (505) 476-4375



Version 07.03.08

NMED USE ONLY	
DTS	
TEMPO	

REPORTING SUBMITTAL FORM

NMED USE ONLY	
Staff	
Admin	

PLEASE NOTE: ® - Indicates required field

SECTION I - GENERAL COMPANY AND FACILITY INFORMATION					
A. ® Company Name: Sterigenics U.S., LLC			D. ® Facility Name: Santa Teresa Facility		
B.1 ® Company Address: 2015 Spring Rd., Ste 650			E.1 ® Facility Address: 2400 Airport Road		
B.2 ® City: Oak Brook	B.3 ® State: IL	B.4 ® Zip: 60523 ¹	E.2 ® City: Santa Teresa	E.3 ® State: NM	E.4 ® Zip: 88008
C.1 ® Company Environmental Contact: Jeffrey Smith		C.2 ® Title: EHS Manager	F.1 ® Facility Contact: Steve Ortiz		F.2 ® Title: General Manager
C.3 ® Phone Number: 847/263-3499		C.4 ® Fax Number: 847/855-6123	F.3 ® Phone Number: 575/589-9300		F.4 ® Fax Number: FORMTEXT 575/589-9729
C.5 ® Email Address: JPSmith@Sterigenics.com			F.5 ® Email Address: SOrtiz@Sterigenics.com		
G. Responsible Official: (Title V only):		H. Title:		I. Phone Number:	
				J. Fax Number:	
K. ® AI Number: 127-PRN20090001	L. Title V Permit Number:		M. Title V Permit Issue Date:	N. NSR Permit Number: NPR-0733M-15	O. NSR Permit Issue Date:
P. Reporting Period: From: 1/1/2014 To: 6/30/2014			OR	Q. Proposed Test Date:	OR
				R. Actual Test Date:	

SECTION II - TYPE OF SUBMITTAL (check one that applies)				
A. <input type="checkbox"/>	Title V Annual Compliance Certification	Permit Condition(s):	Description:	
B. <input type="checkbox"/>	Title V Semi-annual Monitoring Report	Permit Condition(s):	Description:	
C. <input type="checkbox"/>	NSPS Requirement (40CFR60)	Regulation:	Section(s):	Description:
D. <input checked="" type="checkbox"/>	MACT Requirement (40CFR63)	Regulation: Subpart A	Section(s): 63.10(e)(3)	Description: Summary Report-Gaseous and Opacity Excess Emission
E. <input type="checkbox"/>	NMAC Requirement (20.2.xx) or NESHAP Requirement (40CFR61)	Regulation:	Section(s):	Description:
F. <input type="checkbox"/>	Permit or Notice of Intent (NOI) Requirement	Permit No. <input type="checkbox"/> or NOI No. <input type="checkbox"/>	Condition(s):	Description:
G. <input type="checkbox"/>	Requirement of an Enforcement Action	NOV No. <input type="checkbox"/> or SFO No. <input type="checkbox"/> or CD No. <input type="checkbox"/> or Other <input type="checkbox"/>	Section(s):	Description:

SECTION III - PERIODIC EMISSIONS TEST NOTIFICATIONS, TEST PROTOCOLS AND TEST REPORTS (if applicable)					
T. <input type="checkbox"/>	A. Test Report <input type="checkbox"/> CMT: _____		B. Test Protocol <input type="checkbox"/>	C. Notification <input type="checkbox"/> CMT: _____	Description: (Emission Units to be Tested)
	D. Test (EPA Methods) <input type="checkbox"/>	E. Test (EPA Methods) <input type="checkbox"/>	F. RATA Test <input type="checkbox"/>	G. Opacity Test <input type="checkbox"/>	
				H. Portable Analyzer (Periodic Test) <input type="checkbox"/>	

SECTION IV - CERTIFICATION			
After reasonable inquiry, I <u>Kathleen Hoffman</u> certify that the information in this submittal is true, accurate and complete. (name of reporting official)			
® Signature of Reporting Official: <u>Kathleen Hoffman</u>		® Title: SR. VP -Global EHS	® Date: 7/21/14
		® Responsible Official for Title V? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

Reviewed By: _____

Date Reviewed: _____

ED_005212_00004260-00083



11 0000472541

RECEIVED
US EPA, DALLAS, TX
ASSOCIATE DIRECTOR

A1/A1/CO

16 FEB -1 PM 3:39

COMPLIANCE ASSURANCE
& ENFORCEMENT DIV.

110000472541

NM V.8

January 27, 2016

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: Summary Report -Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: July 1, 2015 - December 31, 2015
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The Santa Teresa facility encountered breakdowns of the catalytic oxidizer totaling less than 3 hours, but the breakdowns of the control equipment did not result in uncontrolled emissions being emitted to the atmosphere.

The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide
- (C) Reporting Period Dates
Beginning: July 1, 2015
Ending: December 31, 2015
- (D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and chamber backvents are treated in a catalytic oxidizer system.
- (E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
--------------	-------------------	-----------------------



New Mexico Environment Department
Air Quality Bureau
Compliance and Enforcement Section
525 Camino de los Marquez, Suite 1
Santa Fe, NM 87505
Phone (505) 476-4300 Fax (505) 476-4375



Version 05.02.13

NMED USE ONLY	
TEMPO	

REPORTING SUBMITTAL FORM

NMED USE ONLY	
Staff	
Admin	

PLEASE NOTE: ® - Indicates required field

SECTION I - GENERAL COMPANY AND FACILITY INFORMATION					
A. ® Company Name: Sterigenics U.S. LLC			D. ® Facility Name: Santa Teresa Facility		
B.1 ® Company Address: 2015 Spring Road, Ste 650			E.1 ® Facility Address: 2400 Airport Road		
B.2 ® City: Oak Brook	B.3 ® State: IL	B.4 ® Zip: 60523 ¹	E.2 ® City: Santa Teresa	E.3 ® State: NM	E.4 ® Zip: 88008
C.1 ® Company Environmental Contact: Laura Hartman		C.2 ® Title: EHS Manager	F.1 ® Facility Contact: Steve Ortiz		F.2 ® Title: General Manager
C.3 ® Phone Number: 630-928-1724		C.4 ® Fax Number: 847-855-6123	F.3 ® Phone Number: 575-589-9300		F.4 ® Fax Number: 575-589-9729
C.5 ® Email Address: LHartman@Sterigenics.com			F.5 ® Email Address: SOrtiz@Sterigenics.com		
G. Responsible Official: (Title V only):		H. Title:	I. Phone Number:		J. Fax Number:
K. ® AI Number: 127-PRN2014001	L. Title V Permit Number:	M. Title V Permit Issue Date:	N. NSR Permit Number: 0733-M15-R1		O. NSR Permit Issue Date: 12/23/2014
P. Reporting Period: From: July 1, 2015 To: December 31, 2015					

SECTION II - TYPE OF SUBMITTAL (check one that applies)				
A. <input type="checkbox"/>	Title V Annual Compliance Certification	Permit Condition(s):	Description:	
B. <input type="checkbox"/>	Title V Semi-annual Monitoring Report	Permit Condition(s):	Description:	
C. <input type="checkbox"/>	NSPS Requirement (40CFR60)	Regulation:	Section(s):	Description:
D. <input checked="" type="checkbox"/>	MACT Requirement (40CFR63)	Regulation: Subpart A	Section(s): 63.10(e)(3)	Description: Summary Report-Gaseous and Opacity Excess Emission
E. <input type="checkbox"/>	NMAC Requirement (20.2.xx) or NESHAP Requirement (40CFR61)	Regulation:	Section(s):	Description:
F. <input type="checkbox"/>	Permit or Notice of Intent (NOI) Requirement	Permit No. <input type="checkbox"/> : or NOI No. <input type="checkbox"/> :	Condition(s):	Description:
G. <input type="checkbox"/>	Requirement of an Enforcement Action	NOV No. <input type="checkbox"/> : or SFO No. <input type="checkbox"/> : or CD No. <input type="checkbox"/> : or Other <input type="checkbox"/> :	Section(s):	Description:

SECTION IV - CERTIFICATION			
After reasonable inquiry, I <u>Kathleen Hoffman</u> certify that the information in this submittal is true, accurate and complete. (name of reporting official)			
® Signature of Reporting Official: <u>Kathleen Hoffman</u>		® Title: SR, VP - Global EHS	® Date: 1/27/2016
		® Responsible Official for Title V? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Reviewed By: _____

Date Reviewed: _____

ED_005212_00004260-00085



AI/AI/CO

110000472541

RECEIVE

FEB - 3 2015

January 30, 2015

Air Toxics & Inspection
Coordination Branch
6EN-ADirector - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: **Summary Report –Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: July 1, 2014 – December 31, 2014**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source

Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant

Ethylene Oxide

(C) Reporting Period Dates

Beginning: July 1, 2014
Ending: December 31, 2014

(D) Description of Process Units

The facility employs 13 ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and four chamber backvents are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00086



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell TV5 ST01	TVMP-EO-80000- EOO-F10-000000-00	0125Y151102800001W

(G) Date of Latest CMS Certification or Audit
Dec 1, 2014

(H) Total Operating Time of Affected Source during Reporting Period
4405 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary
There were no emission system CMS instrumentation outages during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
There have been no changes to the CMS, process or controls since the last reporting period.

(L) Responsible Official Certification
Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

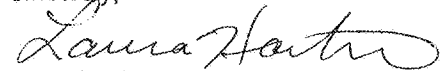


Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report
January 30, 2015

If you have any questions regarding this report, please contact Laura Hartman at either (630) 928-1724 or LHartman@Sterigenics.com.

Sincerely,



Laura Hartman
EHS Manager

Cc: Manager, Compliance and Enforcement Section – New Mexico AQB
Mr. Steve Ortiz – Santa Teresa General Manager

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

✓ 0000 47254/
RECEIVE

July 20, 2015

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733JUL 27 2015
Air Toxics & Inspection
Coordination Branch
6EN-A
AI/AI/CO

RE: **Summary Report –Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: January 1, 2015 – June 30, 2015**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: January 1, 2015
Ending: June 30, 2015

(D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and chamber backvents are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00088



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart recorder	Truline DR450T	8939760945047

(G) Date of Latest CMS Certification or Audit
December 1, 2014

(H) Total Operating Time of Affected Source during Reporting Period
4223 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

There were no emission system CMS instrumentation outages during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period

There have been no changes to the CMS, process or controls since the last reporting period.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

Kathleen Hoffman

Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report
July 20, 2015

If you have any questions regarding this report, please contact Laura Hartman at either (630) 928-1724 or LHartman@Sterigenics.com.

Sincerely,

Laura Hartman

Laura Hartman
EHS Manager

Cc: Manager, Compliance and Enforcement Section – New Mexico AQB
Mr. Steve Ortiz – Santa Teresa General Manager

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

✓ 0000 47254/
RECEIVE

July 20, 2015

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733JUL 27 2015
Air Toxics & Inspection
Coordination Branch
6EN-A
AI/AI/CO

RE: **Summary Report –Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: January 1, 2015 – June 30, 2015**
Sterigenics' Santa Teresa, NM Facility

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide
- (C) Reporting Period Dates
Beginning: January 1, 2015
Ending: June 30, 2015
- (D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and chamber backvents are treated in a catalytic oxidizer system.
- (E) Emission and Operating Parameter Limitations Specified in Permit or Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Catalytic Oxidizer	Catalytic bed temperature	Continuously monitor temp: $\geq 240^{\circ}\text{F}$
	Oxidizer control efficiency	System efficiency $\geq 99\%$
Ceilcote Acid-Wet Scrubber	Scrubber tank liquid level	Record weekly ≤ 115 inches
	Scrubber liquor pH	$\text{pH} \leq 2.0$
	Scrubber liquor temperature	Liquor temp $\leq 120^{\circ}\text{F}$
	Scrubber gas flow rate	Flow rate ≤ 2500 scfm @ 90°F
	Scrubber gas inlet temperature	Inlet temperature $\leq 180^{\circ}\text{F}$
	Scrubber control efficiency	System efficiency $\geq 99.3\%$

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com

ED_005212_00004260-00090



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart recorder	Truline DR450T	8939760945047

(G) Date of Latest CMS Certification or Audit
December 1, 2014

(H) Total Operating Time of Affected Source during Reporting Period
4223 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

There were no emission system CMS instrumentation outages during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period

There have been no changes to the CMS, process or controls since the last reporting period.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

Kathleen Hoffman

Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report
July 20, 2015

If you have any questions regarding this report, please contact Laura Hartman at either (630) 928-1724 or LHartman@Sterigenics.com.

Sincerely,

Laura Hartman

Laura Hartman
EHS Manager

Cc: Manager, Compliance and Enforcement Section – New Mexico AQB
Mr. Steve Ortiz – Santa Teresa General Manager

Sterigenics International, Inc.
2015 Spring Road, Suite 650 • Oakbrook, IL 60523
Tel 800.472.4508 • Fax 630.928.1701 • www.sterigenics.com



AY/AY/CO

1 / 0000 472541

RECEIVED
US EPA, DALLAS, TX
ASSOCIATE DIRECTOR

NS91

V8

16 JUL 26 AM 11:44

COMPLIANCE ASSURANCE
& ENFORCEMENT DIV.

July 25, 2016

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

**RE: Summary Report -Gaseous and Opacity Excess Emission and Continuous Monitoring System Performance for the period: January 1, 2016 - June 30, 2016
Sterigenics' Santa Teresa, NM Facility**

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3), herein is the Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for this facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The Santa Teresa facility encountered breakdowns of the catalytic oxidizer totaling less than 5 hours, but the breakdowns of the control equipment did not result in uncontrolled emissions being emitted to the atmosphere.

The following information is submitted as required in §63.10(e)(3)(vi):

- (A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008
- (B) Identification of Hazardous Air Pollutant
Ethylene Oxide
- (C) Reporting Period Dates
Beginning: January 1, 2016
Ending: June 30, 2016
- (D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms and chamber backvents are treated in a catalytic oxidizer system.



AI/AI/CO

110000472541

RECEIVE

NS41
5/1
6

January 22, 2014

Director Air, Pesticides and Toxics
US EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

24 2014
Air/Toxics & Inspection
Coordination Branch
6EN-A

**RE: Notification of Compliance Status
Sterigenics' Santa Teresa, NM Facility**

Dear Sir:

This Notification of Compliance Status is being sent pursuant to 40 CFR 63.9(h) for Sterigenics' Santa Teresa, New Mexico facility. The facility is subject to the MACT emission standards in Section 63.362. On December 4, 2013 the facility's catalytic oxidizer system underwent performance testing. The results from that testing are contained herein.

Facility Name:

Sterigenics U.S., LLC -- Santa Teresa Facility
2400 Airport Road
Santa Teresa, NM 88008

Method(s) Used to Determine Compliance - Section 63.9(h)(A)

Performance testing of the facility's catalytic oxidizer was conducted on December 4, 2013 in accordance with the test methods stated in 40 CFR 63.365 for Ethylene Oxide Sterilization Facilities.

Performance Test Results - Section 63.9(h)(B)

The catalytic oxidizer system (Donaldson abator) demonstrated an average efficiency of 99.986% for controlling ethylene oxide emissions, versus the 99.0% control standard in Section 63.362.

Methods to be Used for Determining Continued Compliance Section 63.9(h)(C)

The facility assures continued compliance with Section 63.362 standards by measuring / recording scrubber system pH and liquor tank level on a daily and weekly basis, respectively, and catalytic oxidizer bed temperature on a continuous basis.

Type and Quantity of Hazardous Air Pollutants Emitted During Reporting Period - Section 63.9(h)(D)

The Santa Teresa facility used approximately 1,034,298 pounds of ethylene oxide during all of 2013. Approximately 95% of that amount (982,583 pounds) is emitted from sterilization chamber vents (via vacuum pumps) to the Ceilcote wet scrubber system. Using the 99.954% control efficiency from the most recent Ceilcote system performance test conducted on December 12, 2013, calculated process emissions are approximately 452 pounds per year. Approximately 4% of the ethylene oxide (41,372 pounds) is vented from the facility's aeration rooms/cells and treated by the catalytic oxidizer emission control system. Using the 99.986% demonstrated control efficiency achieved during the December 4th test, treated emissions from the aeration rooms total approximately 6 pounds annually. Prior to October 2013, backvent process emissions representing approximately 1% of the facility's total ethylene oxide usage (or 10,342 pounds), were not required to be controlled. The facility's new NSR air permit issued last June now requires backvent emission controls on the facility's four largest chambers. Calculated backvent emissions for 2013 totaled 9,112 pounds. In total, the facility's ethylene oxide emissions during 2013 were 9570 pounds (4.8 tons).



Analysis Demonstrating Whether Source is a Major Source - Section 63.9(h)(E)

Based on the above emission analysis, the facility emits less than 10 tons/year of ethylene oxide and is an area source.

Description of Air Pollution Control Device & Control Efficiency for Facility's Emission Points - Section 63.9(h)(F)

A wet scrubber emission control device is used for controlling emissions from the facility's sterilization vents/vacuum pumps. The Ceilcote scrubber system demonstrated a control efficiency of 99.954% on December 12, 2012. Process emissions from the facility's aeration rooms/cells and 4 of the facility's thirteen sterilization chamber backvents are controlled by a catalytic oxidizer operating at a 99.986% performance efficiency. The facility's other chamber backvent emissions are not controlled.

Statement by Owner as to Whether the Facility Has Complied with the Relevant Standard - Section 63.9(h)(G)

To the best of our knowledge, the Santa Teresa facility has operated in compliance with the applicable standards in 40 CFR Part 63, Subpart O.

Certification Statement:

To the best of the undersigned's knowledge, information and belief formed after reasonable inquiry, the information submitted in this notification of the compliance status for Sterigenics' Santa Teresa, New Mexico facility is true, accurate, and complete.

Kathleen Hoffman
Signature

Kathleen Hoffman
Printed Name

Senior Vice President - Global EHS
Title

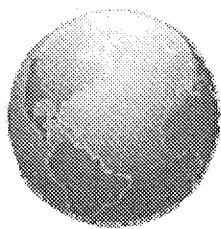
22-Jun-2014
Date

If you should need further information, please contact Mr. Jeffrey Smith at (847) 263-3499 or JPSmith@Sterigenics.com.

Sincerely,

Jeffrey P. Smith
Jeffrey P. Smith
EHS Manager

Cc: Manager, Compliance and Enforcement Section - New Mexico AQB
Mr. Steve Ortiz - Santa Teresa General Manager



ECSI

"Your Regulatory Compliance Expert"

- December 4, 2013

Mr. Jeff Smith
Manager, Environmental Health and Safety
STERIGENICS, INC.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Subject: **RESULTS OF ETHYLENE OXIDE SOURCE TESTING PERFORMED AT THE STERIGENICS, INC. FACILITY IN SANTA TERESA, NEW MEXICO**

Dear Mr. Smith:

Please find attached the a presentation of the results of the ethylene oxide source testing performed at your Santa Teresa facility by ECSI, Inc. on Wednesday, December 4, 2013. These test results are to be kept with all records pertaining to NMED-required testing of the EtO gas-sterilization system, and are to be made available upon request by the NMED. A bound copy of the final source test report, complete with all raw test data, will follow this submittal in the mail. A copy of the final report will also be submitted on your behalf to the NMED

The test results indicate that you continue to operate your EtO sterilization and emission-control system in compliance with NMED requirements.

If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSI



AI/AI/CO

Thompson

110000472541

4/6/8/3

RECEIVE

January 23, 2015

John Blevins
Director ~ Compliance Assurance and Enforcement
EPA Region VI
1445 Ross Avenue, Suite 1200
Mail Code: 6EN
Dallas, TX 75202-2733

FEB - 3 2015

AirToxics & Inspection
Coordination Branch
6EN-A

**RE: Summary Report - Excess Gaseous Emissions and Continuous Monitoring System
Performance, Sterigenics Grand Prairie, Texas Facility - July 1, 2014 to December 31, 2014**

Dear Mr. Blevins:

As required by 40 CFR 63.366(a) (3), Sterigenics U.S., LLC is submitting this semi-annual excess emissions and continuous monitoring system summary report for our Grand Prairie, Texas facility.

40 CFR 63.10(e)(3)(vii) states: "If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is less than 1 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 5 percent of the total operating time for the reporting period, only the summary report shall be submitted, and the full excess emissions and continuous monitoring system performance report need not be submitted unless required by the Administrator".

As set forth in the above cited regulation, we are submitting this summary report for our Grand Prairie facility because:

1. The total duration of excess emissions and the process or control system parameter exceedances for the reporting period was zero (0) hours which is less than 1 percent of the total operating time for the reporting period, and
2. CMS downtime for the reporting period was zero (0) hours, which is less than 5 percent of the total operating time for the reporting period. This facility is not required to have any Continuous Monitoring systems (CMS).

Sterigenics U.S., LLC has reviewed all applicable provisions of the operating permit. The following information is submitted as required in §63.10(e) (3) (vi):

(A) Company Name and Address of the Affected Source

Sterigenics U.S., LLC
1302 Avenue T
Grand Prairie, TX 75050

(B) Identification of Hazardous Air Pollutant

Ethylene Oxide

(C) Reporting Period Dates

Beginning: July 01, 2014

Ending: December 31, 2014

(D) Description of Process Units

The facility process units are sterilization process chambers of various sizes using ethylene oxide as the sterilant gas. Ethylene oxide process emissions are vented to an acid-water scrubber.

(E) Emission and Operating Parameter Limitations Specified in Relevant Standards

<u>Control Unit</u>	<u>Control Parameter</u>	<u>Limitations/Standards</u>
Scrubber	Scrubber tank liquid level	Record weekly/ <146.5 inches *

* 40 CFR 63.364 (b) requires that sterilization facilities using an acid-water scrubber shall either record the concentration of the scrubber liquor **or** the level of the scrubber liquor. The current permit issued requires weekly monitoring of the tank level.

(F) Monitoring Equipment Manufacturer(s) and model numbers.

Advanced Air Technologies (AAT) wet scrubber. Job No. 021105

(G) Date of Latest CMS Certification or Audit

N/A

(H) Total Operating Time of Affected Source during Reporting Period

Continuous, for a total of 4,407 hours.

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Scrubber	0 hr.	0%	0	0	0	0	0

(J) CMS Performance Summary

Liquor level in the scrubber tank was recorded weekly and did not exceed permitted parameters during this reporting period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period

None.



A1/A1/co

110000472541

436623

RECEIVE

FEB 1 2013

Air/Toxics & Inspection
Coordination Branch
6EN-A

January 25, 2013

Director - Air, Pesticides and Toxics
EPA Region VI
1445 Ross Avenue
Dallas, TX 75202-2733

RE: **Summary Report - Gaseous and Opacity Excess Emission and Continuous Monitoring
System Performance**
For the period: July 1, 2012 – December 31, 2012
Sterigenics' Santa Teresa, NM Plant

Dear Director:

Per the requirements in 40 CFR 63.10(e)(3)(vi), herein is the semi-annual Summary Report for our Santa Teresa, New Mexico facility.

As provided in 40 CFR 63.10(e)(3)(vii), we are submitting only the Summary Report for our Santa Teresa facility because:

1. The total duration of excess emissions, or process or control system parameter exceedances during the reporting period was less than 1 percent of the total operating time, and
2. CMS downtime during the reporting period was less than 5 percent of the total operating time.

The following information is submitted as required in §63.10(e)(3)(vi):

(A) Company Name and Address of the Affected Source
Sterigenics US, LLC
2400 Airport Road
Santa Teresa, NM 88008

(B) Identification of Hazardous Air Pollutant
Ethylene Oxide

(C) Reporting Period Dates
Beginning: July 1, 2012
Ending: December 31, 2012

(D) Description of Process Units
The facility employs ethylene oxide/propylene oxide sterilization chambers of various sizes to process medical devices and other products. Process emissions from the facility's sterilization chambers are treated in a Ceilcote acid-water scrubber system. Process emissions from the facility's aeration rooms are treated in a catalytic oxidizer system.

(E) Emission and Operating Parameter Limitations Specified in Relevant Standards

Control Unit	Control Parameter	Limitations/Standards
Abator	Catalytic bed temperature	Continuously monitor: >240°F
Scrubber	Scrubber tank liquid level	Record weekly



(F) Monitoring Equipment Manufacturers and Model Numbers

<u>Monitoring Equipment</u>	<u>Model Number</u>	<u>Serial Number</u>
Honeywell Chart Recorder	TVMP-EO-800-000	0125Y151102800001W

(G) Date of Latest CMS Certification or Audit
Not applicable

(H) Total Operating Time of Affected Source during Reporting Period
4402 hours

(I) Emission Data Summary

<u>Control Unit</u>	<u>Total Duration of Excess Emissions</u>	<u>Excess Emission Duration as % of Total Hours</u>	<u>Excess Emission Duration by Cause (hours)</u>				
			<u>Startup/Shutdown</u>	<u>Control Equipment Problems</u>	<u>Process Problems</u>	<u>Other Known Causes</u>	<u>Other Unknown Causes</u>
Abator	0 hr	0%	0	0	0	0	0
Scrubber	0 hr	0%	0	0	0	0	0

(J) CMS Performance Summary

There were no instrumentation outages of the emission treatment systems during the period.

(K) Description of Changes in CMS, Processes or Controls since Last Reporting Period
None.

(L) Responsible Official Certification

Based on the information and belief formed after reasonable inquiry, the statements and information in this report are true, accurate, and complete.

Kathleen Hoffman
Sr. Vice President – Global EHS

(M) Date of Report
January 25, 2013

If you have any questions regarding this report, please contact Jeffrey Smith at either (847) 263-3499 or JPSmith@Sterigenics.com.

Sincerely,

Jeffrey Smith
EHS Manager



11 0006472541

RECEIVED
US EPA, DALLAS, TX
ASSOCIATE DIRECTOR

16 SEP -6 AM 9:17

COMPLIANCE ASSURANCE
& ENFORCEMENT DIV.

A1/A1/C

September 2, 2016

Director- Air, Pesticides & Toxics
US EPA Region VI
1445 Ross Avenue
Dallas, Texas 75202-2733

RE: Notification of Scheduled Emission System Performance Test
Sterigenics' Santa Teresa, New Mexico Facility
NSR Permit No: 0733-M15-R1

Dear Sir:

Please be advised the annual performance test of the catalytic oxidizer emission control system at our Santa Teresa, NM facility will occur on November 15, 2016 at approximately 10 am. The facility is located at:

2400 Airport Road
Santa Teresa, NM 88008

This notification is being provided per 40 CFR 63.9(e). The annual oxidizer performance test is being done pursuant to 40 CFR 63.363(b)(4)(i).

Please call me at (630) 928-1724 if you have any questions.

Sincerely,



Laura Hartman
EHS Manager

cc: Steve Ortiz, Santa Teresa Facility General Manager

**TEST PROTOCOL FOR
AIR POLLUTION SOURCE TESTING
OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO**

Submitted to:

**NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, New Mexico, 87505-1816**

Submitted by:

**STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008**

Prepared by:

**ECSI, INC.
PO Box 848
San Clemente, California 92674-0848**

August 10, 2016

ECSI

CONTACT SUMMARY

CLIENT

Ms. Laura Hartman
Environmental Health and Safety
STERIGENICS U.S., LLC.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Phone: (630)928-1724
email: LHartman@sterigenics.com

SOURCE LOCATION

Mr. Steve Ortiz
General Manager
STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008

Phone: (575)589-9300
email: SOrtiz@sterigenics.com

PROPOSED TEST DATE

November 15, 2016

REGULATORY AGENCY

NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, New Mexico, 87505-1816

Phone: (505)476-4300
FAX: (505)476-4375
email: Stacktest.aqb@state.nm.us

TESTING CONTRACTOR

Daniel P. Kremer
Project Manager
ECSi, Inc.
PO Box 848
San Clemente, California 92674-0848

Phone: (949)400-9145
FAX: (949)281-2169
email: dankremer@ecsi1.com

ECSi

TABLE OF CONTENTS

	<u>PAGE NO.</u>
CONTACT SUMMARY	i
TABLE OF CONTENTS	ii
1.0 INTRODUCTION	1
2.0 EQUIPMENT	2
3.0 TESTING	3
4.0 RULE/COMPLIANCE REQUIREMENTS	4
5.0 TEST METHOD REFERENCE	5
5.1 Summary/Introduction	5
5.2 EtO Control Efficiency Measurement	5
5.3 Sample Transport	6
5.4 GC Injection	6
5.5 GC Conditions	6
5.6 Calibration Standards	6
5.7 Sampling Duration	7
5.8 Control Efficiency Calculations	7
6.0 TEST SCENARIO	8
7.0 QA/QC	9
7.1 Field Testing Quality Assurance	9
7.2 Calibration Procedures	9
8.0 FINAL TEST REPORT DESCRIPTION	10

1.0 INTRODUCTION

ECSi, Inc. proposes to conduct air pollution source testing of an ethylene oxide (EtO) emission-control system operated by Sterigenics U.S., LLC. in Santa Teresa, New Mexico. The control device to be tested is Donaldson Abator catalytic oxidizer, which is currently used to control emissions from two aeration rooms and all 13 sterilization chamber backvents. The purpose of the testing program will be to evaluate continued compliance with EPA requirements under the current National Emissions Standards for Hazardous Air Pollutants (NESHAP), and with the requirements specified in the New Source Review Permit, #0733-M15-R1, issued by the New Mexico Environment Department (NMED).

2.0 EQUIPMENT

The EtO gas-sterilization system is comprised of thirteen commercial sterilizers, all discharging through liquid-ring vacuum pumps to a packed-tower acid scrubber emission control device. Two aeration rooms and thirteen sterilization chamber backvents are all discharged to a Donaldson Abator catalytic oxidizer emission-control device. The gas-sterilization and emission-control equipment consist of the following:

- Thirteen Gas Sterilizers, each comprised of a steam-heated sterilization chamber (varying in size from 13-30 pallet capacity), a liquid ring recirculating vacuum pump chamber evacuation system ("chamber vacuum vent"), and a backdraft valve ("chamber exhaust vent");
- Two aeration rooms, each comprised of a heated aeration chamber and an exhaust system

Sterilizer vacuum pump emissions are controlled by:

- One packed-tower chemical scrubber, equipped with a packed reaction/interface column, a scrubber fluid recirculation system, a scrubber fluid reaction/storage tank, and a dedicated blower exhaust system.

Aeration room and sterilizer backvent emissions are controlled by:

- One Donaldson EtO Abator catalytic oxidizer, 20,000 SCFM, equipped with a prefilter, a gas-fired heater, an exhaust gas heat exchanger, a reactive catalyst bed, and an exhaust blower.

3.0 TESTING

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365(d)(2). EtO concentration measurement for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO concentration at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product. The testing program will be conducted in accordance with the procedures outlined in the following sections.

4.0 RULE/COMPLIANCE REQUIREMENTS

The EtO gas-sterilization system at Sterigenics U.S., LLC. is being tested to determine compliance with the current federal EPA National Emissions Standard for Hazardous Air Pollutants (NESHAP) for ethylene oxide, and with NMED requirements. The current testing will demonstrate continued compliance with the following requirements:

- The emissions from the aeration process must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.
- The emissions from the sterilizer backvents must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.

Testing is required to demonstrate compliance with these requirements. Source testing of the emission-control device is required annually, in accordance with NMED requirements.

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365(d)(2), using EPA Method 18 as specified in 40CFR, Part 60, Appendix A. EtO concentration measurement for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO concentration at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product.

Operation and documentation of process conditions will be performed by personnel from Sterigenics using existing monitoring instruments installed by the manufacturer on the equipment to be tested. In accordance with USEPA CFR40, Part 63.364 (c), catalyst bed temperature will be recorded.

5.2 ETO CONTROL EFFICIENCY MEASUREMENT

During aeration and backvent testing, EtO concentration at the inlet and outlet of the catalytic oxidizer will be determined using direct source sample injection into the GC. Since the source gas flow is identical at the inlet and outlet of the catalytic oxidizer control-efficiency of EtO during aeration and backvent will be calculated by comparing the concentration of EtO vented to the system inlet to the concentration of EtO vented from the system outlet.

During aeration and backvent, vented gas will be analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) will be used to quantify inlet EtO concentration, and a photoionization detector (PID) will be used to quantify low-level EtO concentration at the emission-control device outlet.

5.3 SAMPLE TRANSPORT

Source gas will be pumped to the GC at approximately 500-1000 cubic centimeters per minute (cc/min) from the sampling ports through two lengths of Teflon® sample line, each with a nominal volume of approximately 75 cubic centimeters (cc) and an outer diameter of 0.25 inch. At the inlet of the catalytic oxidizer, the sampling port is a manifold installed by the equipment manufacturer, and is located in the plenum immediately upstream of the oxidizer catalyst bed. At the outlet of the catalytic oxidizer, sampling ports will be located in the exhaust stack downstream of the catalyst bed.

5.4 GC INJECTION

Source-gas samples will then be injected into the GC which will be equipped with two heated sampling loops, each containing a volume of approximately 2cc and maintained at 100 degrees Celsius (C). Injections will occur at approximately one-minute intervals during backvent testing, and at approximately five-minute intervals during aeration testing. Helium will be the carrier gas for both the FID and PID.

5.5 GC CONDITIONS

The packed columns for the GC will both be operated at 80 degrees C. The columns will be stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

During the analysis, the FID will be operated at 250 degrees C. The support gases for the FID will be hydrogen (99.995% pure) and air (99.9999% pure). Any unused sample gas will be vented from the GC system back to the inlet of the control device being tested.

5.6 CALIBRATION STANDARDS

The FID will be calibrated for mid-range part-per-million-by-volume (ppmv) level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

The PID will be calibrated for low-range ppmv level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

Each of these calibration standards will be in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates will be included with the final report.

5.7 SAMPLING DURATION

Since aeration is a 24-hour process at this facility, with constant discharge flow from the aeration chambers to the emission-control system, aeration testing will consist of three 1-hour test runs. Each test run will be performed with recently sterilized product in the aeration chambers. Backvent testing will consist of one 15-minute test run, which encompasses the entire duration of the backvent process. The test run will be performed with recently sterilized product in the sterilization chamber.

5.9 CONTROL-EFFICIENCY CALCULATIONS

Control efficiency of EtO will be calculated for aeration and backvent. Results of the control-efficiency testing will be summarized in the final report.

6.0 TEST SCENARIO

The aeration and backvent testing will be performed during normal process load conditions. Three aeration test runs and one backvent test run will be conducted in series to verify the performance of the emission-control device. The testing schedule is as follows:

- 1) Testing equipment is set up and calibrated.
- 2) Backvent Test Run #1 is conducted at the conclusion of the sterilization cycle of one the 13 sterilizers. Sampling is performed at the inlet and the outlet of the catalytic oxidizer. Sterilized product is then transferred into aeration.
- 3) Aeration Phase Test Run #1 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 4) Aeration Phase Test Run #2 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 5) Aeration Phase Test Run #3 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 6) Post calibration check is performed, testing equipment is packed.

7.0 QA/QC

7.1 FIELD TESTING QUALITY ASSURANCE

At the beginning of the test, the sampling system will be leak checked at a vacuum of 15 inches of mercury. The sampling system will be considered leak free when the flow indicated by the rotameters falls to zero.

At the beginning of the test, a system blank will be analyzed to ensure that the sampling system is free of EtO. Ambient air will be introduced at the end of the heated sampling line and drawn through the sampling system line to the GC for analysis. The resulting chromatogram also will provide a background level for non-EtO components (i.e. ambient air, carbon dioxide, water vapor) which are present in the source gas stream due to the ambient dilution air which is drawn into the emission-control device, and due to the destruction of EtO by the emission-control device which produces carbon dioxide and water vapor. This chromatogram, designated AMB, will be included with the calibration data in the final report.

7.2 CALIBRATION PROCEDURES

The GC system will be calibrated at the beginning and conclusion of each day's testing. Using the Peaksimple II analytical software, a point-to-point calibration curve will be constructed for each detector. A gas cylinder of similar composition as the calibration gases, but certified by a separate supplier, will be used to verify calibration gas composition and GC performance.

All calibration gases and support gases used will be of the highest purity and quality available. A copy of the laboratory certification for each calibration gas will be included in the final report.

8.0 FINAL TEST REPORT DESCRIPTION

The test results will be summarized in a written report. This report will be submitted to NMED no later than 60 days after the conclusion of the field testing. It will include results for EtO control efficiency of the emission-control system. The report will contain:

- Summary tables with comparisons of the test results to rule limits;
- Copies of all intermediate data tables and calculation worksheets;
- Copies of all GC chromatograms from calibration runs and sample injections; and
- Laboratory calibration certificates for all calibration gases and all applicable measurement instruments.



AI/AI/CO

110000 472541

RECEIVE

NM541V.7

October 1, 2015

Director- Air, Pesticides & Toxics
US EPA Region VI
1445 Ross Avenue
Dallas, Texas 75202-2733

OCT 5 2015

Air Toxics & Inspection
Coordination Branch
6EN-A

RE: Notification of Scheduled Emission System Performance Test
Sterigenics' Santa Teresa, New Mexico Facility
NSR Permit No: 0733-M15-R1

OCT 5 2015

Dear Sir:

Please be advised the annual performance test of the catalytic oxidizer emission control system at our Santa Teresa, NM facility will occur on December 4, 2015 at approximately 10 am. The facility is located at:

2400 Airport Road
Santa Teresa, NM 88008

This notification is being provided per 40 CFR 63.9(e). The annual oxidizer performance test is being done pursuant to 40 CFR 63.363(b)(4)(i).

Please call me at (630) 928-1724 if you have any questions.

Sincerely,

Laura Hartman
EHS Manager

cc: Steve Ortiz, Santa Teresa Facility General Manager

**TEST PROTOCOL FOR
AIR POLLUTION SOURCE TESTING
OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO**

Submitted to:

**NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, New Mexico, 87505-1816**

Submitted by:

**STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008**

Prepared by:

**ECSI, INC.
PO Box 848
San Clemente, California 92674-0848**

September 30, 2015

ECSI

CONTACT SUMMARY

CLIENT

Ms. Laura Hartman
Environmental Health and Safety
STERIGENICS U.S., LLC.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Phone: (630)928-1724
email: LHartman@sterigenics.com

SOURCE LOCATION

Mr. Steve Ortiz
General Manager
STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008

Phone: (575)589-9300
email: SOrtiz@sterigenics.com

PROPOSED TEST DATE

December 4, 2015

REGULATORY AGENCY

NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
525 Camino de los Marquez, Suite 1
Santa Fe, New Mexico, 87505-1816

Phone: (505)476-4300
FAX: (505)476-4375
email: Stacktest.aqb@state.nm.us

TESTING CONTRACTOR

Daniel P. Kremer
Project Manager
ECSi, Inc.
PO Box 848
San Clemente, California 92674-0848

Phone: (949)400-9145
FAX: (949)281-2169
email: dankremer@ecsi1.com

ECSi

TABLE OF CONTENTS

	<u>PAGE NO.</u>
CONTACT SUMMARY	i
TABLE OF CONTENTS	ii
1.0 INTRODUCTION	1
2.0 EQUIPMENT	2
3.0 TESTING	3
4.0 RULE/COMPLIANCE REQUIREMENTS	4
5.0 TEST METHOD REFERENCE	5
5.1 Summary/Introduction	5
5.2 Volumetric Flow Measurement	5
5.3 EtO Mass-Emissions Measurement	5
5.4 Sample Transport	6
5.5 GC Injection	6
5.6 GC Conditions	6
5.7 Calibration Standards	7
5.8 Sampling Duration	7
5.9 Mass-Emissions Calculations	7
6.0 TEST SCENARIO	9
7.0 QA/QC	10
7.1 Field Testing Quality Assurance	10
7.2 Calibration Procedures	10
8.0 FINAL TEST REPORT DESCRIPTION	11

1.0 INTRODUCTION

ECSi, Inc. proposes to conduct air pollution source testing of an ethylene oxide (EtO) emission-control system operated by Sterigenics U.S., LLC. in Santa Teresa, New Mexico. The control device to be tested is Donaldson Abator catalytic oxidizer, which is currently used to control emissions from two aeration rooms and all 13 sterilization chamber backvents. The purpose of the testing program will be to evaluate continued compliance with EPA requirements under the current National Emissions Standards for Hazardous Air Pollutants (NESHAP), and with the requirements specified in the New Source Review Permit, #0733-M15-R1, issued by the New Mexico Environment Department (NMED).

2.0 EQUIPMENT

The EtO gas-sterilization system is comprised of thirteen commercial sterilizers, all discharging through liquid-ring vacuum pumps to a packed-tower acid scrubber emission control device. Two aeration rooms and four sterilization chamber backvents are all discharged to a Donaldson Abator catalytic oxidizer emission-control device. The gas-sterilization and emission-control equipment consist of the following:

- Thirteen Gas Sterilizers, each comprised of a steam-heated sterilization chamber (varying in size from 13-30 pallet capacity), a liquid ring recirculating vacuum pump chamber evacuation system ("chamber vacuum vent"), and a backdraft valve ("chamber exhaust vent");
- Two aeration rooms, each comprised of a heated aeration chamber and an exhaust system

Sterilizer vacuum pump emissions are controlled by:

- One packed-tower chemical scrubber, equipped with a packed reaction/interface column, a scrubber fluid recirculation system, a scrubber fluid reaction/storage tank, and a dedicated blower exhaust system.

Aeration room and sterilizer backvent emissions are controlled by:

- One Donaldson EtO Abator catalytic oxidizer, 20,000 SCFM, equipped with a prefilter, a gas-fired heater, an exhaust gas heat exchanger, a reactive catalyst bed, and an exhaust blower.

3.0 TESTING

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365(d)(2). EtO emissions monitoring for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product. The testing program will be conducted in accordance with the procedures outlined in the following sections.

4.0 RULE/COMPLIANCE REQUIREMENTS

The EtO gas-sterilization system at Sterigenics U.S., LLC. is being tested to determine compliance with the current federal EPA National Emissions Standard for Hazardous Air Pollutants (NESHAP) for ethylene oxide, and with NMED requirements. The current testing will demonstrate continued compliance with the following requirements:

- The emissions from the aeration process must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.
- The emissions from the sterilizer backvents must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.

Testing is required to demonstrate compliance with these requirements. Source testing of the emission-control device is required annually, in accordance with NMED requirements.

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365(d)(2), using EPA Method 18 as specified in 40CFR, Part 60, Appendix A. EtO emissions monitoring for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product.

Operation and documentation of process conditions will be performed by personnel from Sterigenics using existing monitoring instruments installed by the manufacturer on the equipment to be tested. In accordance with USEPA CFR40, Part 63.364 (c), catalyst bed temperature will be recorded.

5.2 VOLUMETRIC FLOW MEASUREMENT

Exhaust gas flow at the outlet of the catalytic oxidizer will be determined by EPA Method 2C using a standard pitot tube and an inclined-oil manometer. Sampling ports will be located far enough from any flow disturbances to permit accurate flow measurement.

Temperature measurements will be obtained from a type K thermocouple and thermometer attached to the sampling probe. Exhaust gas composition will be assumed to be air and small amounts of water vapor. Water vapor will be negligible, at about 3 percent.

5.3 CONTROL EFFICIENCY AND MASS EMISSIONS MEASUREMENT

During aeration and backvent testing, EtO emissions at the inlet and outlet of the catalytic oxidizer will be determined using direct source sample injection into the GC. The mass of EtO emitted to the inlet and from the outlet will be determined using the equation shown below in Section 5.9. Mass-mass control-efficiency

of EtO during aeration and backvent will be calculated by comparing the mass of EtO vented to the system inlet to the mass of EtO vented from the system outlet.

During aeration and backvent, vented gas will be analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) will be used to quantify inlet EtO emissions, and a photoionization detector (PID) will be used to quantify low-level EtO emissions at the emission-control device outlet.

5.4 SAMPLE TRANSPORT

Source gas will be pumped to the GC at approximately 500-1000 cubic centimeters per minute (cc/min) from the sampling ports through two lengths of Teflon® sample line, each with a nominal volume of approximately 75 cubic centimeters (cc) and an outer diameter of 0.25 inch. At the inlet of the catalytic oxidizer, the sampling port will be located in the plenum immediately upstream of the oxidizer catalyst bed. At the outlet of the catalytic oxidizer, sampling ports will be located in the exhaust stack downstream of the catalyst bed.

5.5 GC INJECTION

Source-gas samples will then be injected into the GC which will be equipped with two heated sampling loops, each containing a volume of approximately 2cc and maintained at 100 degrees Celsius (C). Injections will occur at approximately one-minute intervals during backvent testing, and at approximately five-minute intervals during aeration testing. Helium will be the carrier gas for both the FID and PID.

5.6 GC CONDITIONS

The packed columns for the GC will both be operated at 80 degrees C. The columns will be stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

During the analysis, the FID will be operated at 250 degrees C. The support gases for the FID will be hydrogen (99.995% pure) and air (99.9999% pure). Any unused sample gas will be vented from the GC system back to the inlet of the control device being tested.

5.7 CALIBRATION STANDARDS

The FID will be calibrated for mid-range part-per-million-by-volume (ppmv) level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

The PID will be calibrated for low-range ppmv level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

Each of these calibration standards will be in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates will be included with the final report.

5.8 SAMPLING DURATION

Since aeration is a 24-hour process at this facility, with constant discharge flow from the aeration chambers to the emission-control system, aeration testing will consist of three 1-hour test runs. Each test run will be performed with recently sterilized product in the aeration chambers. Backvent testing will consist of one 15-minute test run, which encompasses the entire duration of the backvent process. The test run will be performed with recently sterilized product in the sterilization chamber.

5.9 CONTROL-EFFICIENCY/MASS-EMISSIONS CALCULATIONS

Mass emissions of EtO during aeration will be calculated using the following equation:

$$\text{MassRate} = (\text{VolFlow})(\text{MolWt})(\text{ppmv EtO}/10^6)/(\text{MolVol})$$

Where:

MassRate = EtO mass flow rate, pounds per minute
VolFlow = Corrected volumetric flow rate, standard cubic feet per minute at 68 degrees F
MolWt = 44.05 pounds EtO per pound mole
ppmv EtO = EtO concentration, parts per million by volume
 10^6 = Conversion factor, ppmv per "cubic foot per cubic foot"
MolVol = 385.32 cubic feet per pound mole at one atmosphere and 68 degrees F

Mass-mass control efficiency of EtO will be calculated for aeration and backvent. Results of the control-efficiency testing will be summarized in the final report.

6.0 TEST SCENARIO

The aeration and backvent testing will be performed during normal process load conditions. Three aeration test runs and one backvent test run will be conducted in series to verify the performance of the emission-control device. The testing schedule is as follows:

- 1) Testing equipment is set up and calibrated.
- 2) Backvent Test Run #1 is conducted at the conclusion of the sterilization cycle of one the 13 sterilizers. Sampling is performed at the inlet and the outlet of the catalytic oxidizer. Sterilized product is then transferred into aeration.
- 3) Aeration Phase Test Run #1 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 4) Aeration Phase Test Run #2 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 5) Aeration Phase Test Run #3 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 6) Post calibration check is performed, testing equipment is packed.

7.0 QA/QC

7.1 FIELD TESTING QUALITY ASSURANCE

At the beginning of the test, the sampling system will be leak checked at a vacuum of 15 inches of mercury. The sampling system will be considered leak free when the flow indicated by the rotameters falls to zero.

At the beginning of the test, a system blank will be analyzed to ensure that the sampling system is free of EtO. Ambient air will be introduced at the end of the heated sampling line and drawn through the sampling system line to the GC for analysis. The resulting chromatogram also will provide a background level for non-EtO components (i.e. ambient air, carbon dioxide, water vapor) which are present in the source gas stream due to the ambient dilution air which is drawn into the emission-control device, and due to the destruction of EtO by the emission-control device which produces carbon dioxide and water vapor. This chromatogram, designated AMB, will be included with the calibration data in the final report.

7.2 CALIBRATION PROCEDURES

The GC system will be calibrated at the beginning and conclusion of each day's testing. Using the Peaksimple II analytical software, a point-to-point calibration curve will be constructed for each detector. A gas cylinder of similar composition as the calibration gases, but certified by a separate supplier, will be used to verify calibration gas composition and GC performance.

All calibration gases and support gases used will be of the highest purity and quality available. A copy of the laboratory certification for each calibration gas will be included in the final report.

8.0 FINAL TEST REPORT DESCRIPTION

The test results will be summarized in a written report. This report will be submitted to NMED no later than 60 days after the conclusion of the field testing. It will include results for EtO control efficiency of the emission-control system and mass emissions of EtO to the atmosphere from the emission-control system outlet. The report will contain:

- Summary tables with comparisons of the test results to rule limits;
- Copies of all intermediate data tables and calculation worksheets;
- Copies of all GC chromatograms from calibration runs and sample injections; and
- Laboratory calibration certificates for all calibration gases and all applicable measurement instruments.



21/10/13 10000472541

NSYI

vol 6

RECEIVE

OCT 23 2013

Air/Toxics & Inspection
Coordination Branch
6EN-A

October 2, 2013

Mr. David Garcia - Associate Director
Air/Toxics & Inspection Coordination Branch
US EPA Region 6
1445 Ross Avenue (6EN-AA)
Dallas, Texas 75202-2733

RE: Notification of Scheduled Emission System Performance Test
Sterigenics' Santa Teresa, New Mexico Facility
NSR Permit No: 0733-M15

Dear Sir:

Please be advised that the annual performance test of the catalytic oxidizer emission control system at our Santa Teresa, NM facility will occur on December 4, 2013 at approximately 10 am. The facility is located at:

2400 Airport Road
Santa Teresa, NM 88008

This notification is being provided per 40 CFR 63.9(e). The annual oxidizer performance test is being done pursuant to 40 CFR 63.363(b)(4)(i). Enclosed is the test protocol for the performance test.

Please call me at (847) 263-3499 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey Smith'.

Jeffrey Smith
EHS Manager

encl.

cc: Steve Ortiz, Santa Teresa Facility General Manager

**TEST PROTOCOL FOR
AIR POLLUTION SOURCE TESTING
OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO**

Submitted to:

**NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
1301 Siler Road, Building B
Santa Fe, New Mexico 87507**

Submitted by:

**STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008**

Prepared by:

**ECSI, INC.
PO Box 848
San Clemente, California 92674-0848**

October 2, 2013

ECSI

CONTACT SUMMARY

CLIENT

Mr. Jeff Smith
Environmental Health and Safety
STERIGENICS U.S., LLC.
2015 Spring Road, Suite 650
Oak Brook, Illinois 60523

Phone: (847)263-3499
email: JPSmith@sterigenics.com

SOURCE LOCATION

Mr. Steve Ortiz
General Manager
STERIGENICS U.S., LLC.
2400 Airport Road
Santa Teresa, New Mexico 88008

Phone: (575)589-9300
email: SOrtiz@sterigenics.com

PROPOSED TEST DATE

Wednesday, December 4, 2013

REGULATORY AGENCY

NEW MEXICO ENVIRONMENT DEPARTMENT
Air Quality Bureau
1301 Siler Road, Building B
Santa Fe, New Mexico 87507

Phone: (505)476-4300
FAX: (505)476-4375
email: Stacktest.agb@state.nm.us

TESTING CONTRACTOR

Daniel P. Kremer
Project Manager
ECSi, Inc.
PO Box 848
San Clemente, California 92674-0848

Phone: (949)400-9145
FAX: (949)281-2169
email: dankremer@ecsi1.com

ECSi

TABLE OF CONTENTS

	<u>PAGE NO.</u>
CONTACT SUMMARY	i
TABLE OF CONTENTS	ii
1.0 INTRODUCTION	1
2.0 EQUIPMENT	2
3.0 TESTING	3
4.0 RULE/COMPLIANCE REQUIREMENTS	4
5.0 TEST METHOD REFERENCE	5
5.1 Summary/Introduction	5
5.2 Volumetric Flow Measurement	5
5.3 EtO Mass-Emissions Measurement	5
5.4 Sample Transport	6
5.5 GC Injection	6
5.6 GC Conditions	6
5.7 Calibration Standards	7
5.8 Sampling Duration	7
5.9 Mass-Emissions Calculations	7
6.0 TEST SCENARIO	9
7.0 QA/QC	10
7.1 Field Testing Quality Assurance	10
7.2 Calibration Procedures	10
8.0 FINAL TEST REPORT DESCRIPTION	11

1.0 INTRODUCTION

ECSi, Inc. proposes to conduct air pollution source testing of an ethylene oxide (EtO) emission-control system operated by Sterigenics U.S., LLC. in Santa Teresa, New Mexico. The control device to be tested is Donaldson Abator catalytic oxidizer, which is currently used to control emissions from two aeration rooms and 4 sterilization chamber backvents. The purpose of the testing program will be to evaluate continued compliance with EPA requirements under the current National Emissions Standards for Hazardous Air Pollutants (NESHAP), and with the requirements specified in the New Source Review Permit, #0733-M15, issued by the New Mexico Environment Department (NMED).

2.0 EQUIPMENT

The EtO gas-sterilization system is comprised of thirteen commercial sterilizers, all discharging through dry screw or liquid-ring vacuum pumps to a packed-tower acid scrubber emission control device. Two aeration rooms and four sterilization chamber backvents are all discharged to Donaldson Abator catalytic oxidizer emission-control device. The gas-sterilization and emission-control equipment consists of the following:

- Thirteen Gas Sterilizers, each comprised of a steam-heated sterilization chamber (varying in size from 13-30 pallet capacity), a dry screw or liquid ring recirculating vacuum pump chamber evacuation system ("chamber vacuum vent"), and a backdraft valve ("chamber exhaust vent");
- Two aeration rooms and aeration cells, each comprised of a heated aeration chamber and a chamber exhaust system

Sterilizer vacuum pump emissions are controlled by:

- One packed-tower chemical scrubber, equipped with a packed reaction/interface column, a scrubber fluid recirculation system, a scrubber fluid reaction/storage tank, and a dedicated blower exhaust system.

Aeration room and sterilizer backvent (Sterilizers 8, 9, 10 and 13) emissions are controlled by:

- One Donaldson EtO Abator catalytic oxidizer, 20,000 SCFM, equipped with a prefilter, a gas-fired heater, an exhaust gas heat exchanger, a reactive catalyst bed, and an exhaust blower.

3.0 TESTING

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365. EtO emissions monitoring for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and at least one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product. The testing program will be conducted in accordance with the procedures outlined in the following sections.

4.0 RULE/COMPLIANCE REQUIREMENTS

The EtO gas-sterilization system at Sterigenics U.S., LLC. is being tested to determine compliance with the current federal EPA National Emissions Standard for Hazardous Air Pollutants (NESHAP) for ethylene oxide, and with NMED requirements. The current testing will demonstrate continued compliance with the following requirements:

- The emissions from the aeration process must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.
- The emissions from the backvents of Sterilizers 8, 9, 10, and 13 must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0%.

Testing is required to demonstrate compliance with these requirements. Source testing of the emission-control device is required annually, in accordance with NMED requirements.

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

EtO source testing will be conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365. EtO emissions monitoring for each test run will be conducted simultaneously at the inlet and outlet of the catalytic oxidizer during a one-hour interval of the 24-hour aeration process, and during the 15-minute sterilizer backvent duration. A total of three one-hour aeration test runs and at least one 15-minute backvent test run will be performed.

During aeration and backvent testing, EtO emissions at the inlet and the outlet of the catalytic oxidizer will be determined using direct source sample injection into the gas chromatograph (GC). All aeration and backvent testing will be performed using recently sterilized product.

Operation and documentation of process conditions will be performed by personnel from Sterigenics using existing monitoring instruments installed by the manufacturer on the equipment to be tested. In accordance with the procedures established in USEPA CFR40, Part 63, Subpart O, catalyst bed temperature will be recorded.

5.2 VOLUMETRIC FLOW MEASUREMENT

Exhaust gas flow at the outlet of the catalytic oxidizer and the scrubber will be determined by EPA Method 2C using a standard pitot tube and an inclined-oil manometer. Sampling ports will be located far enough from any flow disturbances to permit accurate flow measurement.

Temperature measurements will be obtained from a type K thermocouple and thermometer attached to the sampling probe. Exhaust gas composition will be assumed to be air and small amounts of water vapor. Water vapor will be negligible, at about 3 percent.

5.3 CONTROL EFFICIENCY AND MASS EMISSIONS MEASUREMENT

During aeration and backvent testing, EtO emissions at the inlet and outlet of the catalytic oxidizer will be determined using direct source sample injection into the GC. The mass of EtO emitted to the inlet and from the outlet will be determined using the equation shown below in Section 5.9. Mass-mass control-efficiency

of EtO during aeration and backvent^{testing} will be calculated by comparing the mass of EtO vented to the system inlet to the mass of EtO vented from the system outlet.

During aeration and backvent^{testing}, vented gas will be analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual columns; and dual detectors. A flame ionization detector (FID) will be used to quantify inlet EtO emissions, and a photoionization detector (PID) will be used to quantify low-level EtO emissions at the emission-control device outlet.

5.4 SAMPLE TRANSPORT

Source gas will be pumped to the GC at approximately 500-1000 cubic centimeters per minute (cc/min) from the sampling ports through two lengths of Teflon® sample line, each with a nominal volume of approximately 75 cubic centimeters (cc) and an outer diameter of 0.25 inch. At the inlet of the catalytic oxidizer, the sampling port will be located in the plenum immediately upstream of the oxidizer catalyst bed. At the outlet of the catalytic oxidizer, sampling ports will be located in the exhaust stack downstream of the catalyst bed.

5.5 GC INJECTION

Source-gas samples will then be injected into the GC which will be equipped with two heated sampling loops, each containing a volume of approximately 2cc and maintained at 100 degrees Celsius (C). Injections will occur at approximately one-minute intervals during backvent testing, and at approximately five-minute intervals during aeration testing. Helium will be the carrier gas for both the FID and PID.

5.6 GC CONDITIONS

The packed columns for the GC will both be operated at 80 degrees C. The columns will be stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

During the analysis, the FID will be operated at 250 degrees C. The support gases for the FID will be hydrogen (99.995% pure) and air (99.9999% pure). Any unused sample gas will be vented from the GC system back to the inlet of the control device being tested.

5.7 CALIBRATION STANDARDS

The FID will be calibrated for mid-range part-per-million-by-volume (ppmv) level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

The PID will be calibrated for low-range ppmv level analysis using gas proportions similar to the following:

- 1) 100 ppmv EtO, balance nitrogen
- 2) 50 ppmv EtO, balance nitrogen (audit gas)
- 3) 10 ppmv EtO, balance nitrogen
- 4) 1 ppmv EtO, balance nitrogen

Each of these calibration standards will be in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates will be included with the final report.

5.8 SAMPLING DURATION

Since aeration is a 24-hour process at this facility, with constant discharge flow from the aeration chambers to the emission-control system, aeration testing will consist of three 1-hour test runs. Each test run will be performed with recently sterilized product in the aeration chambers. Backvent testing will consist of at least 15-minute test run, which encompasses the entire duration of the backvent process. Each test run will be performed with recently sterilized product in the respective sterilization chambers.

5.9

CONTROL-EFFICIENCY/MASS-EMISSIONS CALCULATIONS

Mass emissions of EtO during aeration will be calculated using the following equation:

$$\text{MassRate} = (\text{VolFlow})(\text{MolWt})(\text{ppmv EtO}/10^6)/(\text{MolVol})$$

Where:

- MassRate = EtO mass flow rate, pounds per minute
VolFlow = Corrected volumetric flow rate, standard cubic feet per minute at 68 degrees F
MolWt = 44.05 pounds EtO per pound mole
ppmv EtO = EtO concentration, parts per million by volume
 10^6 = Conversion factor, ppmv per "cubic foot per cubic foot"
MolVol = 385.32 cubic feet per pound mole at one atmosphere and 68 degrees F

Mass-mass control efficiency of EtO will be calculated for aeration and backvent. Results of the control-efficiency testing will be summarized in the final report.

6.0 TEST SCENARIO

The aeration and backvent testing will be performed during normal process load conditions. Three aeration test runs and ^{up to} three backvent test runs will be conducted in series to verify the performance of the emission-control device. The testing schedule is as follows:

- 1) Testing equipment is set up and calibrated.
- 2) Backvent Test Run #1 is conducted at the conclusion of the sterilization cycle of Sterilization Chamber 8, 9, 10, or 13. Sampling is performed at the inlet and the outlet of the catalytic oxidizer. Sterilized product is then transferred into aeration. Up to two additional backvent test runs may be performed dependent on the production schedules of Chambers 8, 9, 10, and 13.
- 3) Aeration Phase Test Run #1 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 4) Aeration Phase Test Run #2 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 5) Aeration Phase Test Run #3 is conducted with recently sterilized product in aeration. Sampling is performed at the inlet and the outlet of the catalytic oxidizer.
- 6) Post calibration check is performed, testing equipment is packed.

7.0 QA/QC

7.1 FIELD TESTING QUALITY ASSURANCE

At the beginning of the test, the sampling system will be leak checked at a vacuum of 15 inches of mercury. The sampling system will be considered leak free when the flow indicated by the rotameters falls to zero.

At the beginning of the test, a system blank will be analyzed to ensure that the sampling system is free of EtO. Ambient air will be introduced at the end of the heated sampling line and drawn through the sampling system line to the GC for analysis. The resulting chromatogram also will provide a background level for non-EtO components (i.e. ambient air, carbon dioxide, water vapor) which are present in the source gas stream due to the ambient dilution air which is drawn into the emission-control device, and due to the destruction of EtO by the emission-control device which produces carbon dioxide and water vapor. This chromatogram, designated AMB, will be included with the calibration data in the final report.

7.2 CALIBRATION PROCEDURES

The GC system will be calibrated at the beginning and conclusion of each day's testing. Using the Peaksimple II analytical software, a point-to-point calibration curve will be constructed for each detector. A gas cylinder of similar composition as the calibration gases, but certified by a separate supplier, will be used to verify calibration gas composition and GC performance.

All calibration gases and support gases used will be of the highest purity and quality available. A copy of the laboratory certification for each calibration gas will be included in the final report.

8.0 FINAL TEST REPORT DESCRIPTION

The test results will be summarized in a written report. This report will be submitted to NMED no later than 60 days after the conclusion of the field testing. It will include results for EtO control efficiency of the emission-control system and mass emissions of EtO to the atmosphere from the emission-control system outlet. The report will contain:

- Summary tables with comparisons of the test results to rule limits;
- Copies of all intermediate data tables and calculation worksheets;
- Copies of all GC chromatograms from calibration runs and sample injections; and
- Laboratory calibration certificates for all calibration gases and all applicable measurement instruments.



ai/aico

110000472541

N541

W/ b

RECEIVE

OCT 23 2013

October 20, 2013

Director, Air Pesticides & Toxics
US EPA Region 6
1445 Ross Avenue
Dallas, Texas 75202-2733

Air/Toxics & Inspection
Coordination Branch
6EN-A

RE: 2nd Notification of Scheduled Emission System Performance Test
Sterigenics' Santa Teresa, New Mexico Facility
NSR Permit No: 0733-M15

Dear Sir:

Notification of our planned performance test of the catalytic oxidizer emission control system at our Santa Teresa, NM facility was sent to EPA Region 6 earlier this month, but was returned to us due to the federal government shutdown (see enclosed FedEx notice). Please be advised that the annual performance test will occur on December 4, 2013 at approximately 10 am. The facility is located at:

2400 Airport Road
Santa Teresa, NM 88008

This notification is being provided per 40 CFR 63.9(e). The annual oxidizer performance test is being done pursuant to 40 CFR 63.363(b)(4)(i). Enclosed is the test protocol for the performance test.

Please call Jeffrey Smith at (847) 263-3499 if you have any questions.

Sincerely,

Sue Reinhardt
EHS Manager

encl.

cc: Steve Ortiz, Santa Teresa Facility General Manager



AI/AI/CO

110000472541

RECEIVE

OCT - 2 2014

Toxics & Inspection
Coordination Branch
6EN-A

September 30, 2014

Director- Air, Pesticides & Toxics
US EPA Region VI
1445 Ross Avenue
Dallas, Texas 75202-2733

RE: Notification of Scheduled Emission System Performance Test
Sterigenics' Santa Teresa, New Mexico Facility
NSR Permit No: 0733-M15

Dear Sir:

Please be advised the annual performance test of the catalytic oxidizer emission control system at our Santa Teresa, NM facility will occur on December 3, 2014 at approximately 10 am. The facility is located at:

2400 Airport Road
Santa Teresa, NM 88008

This notification is being provided per 40 CFR 63.9(e). The annual oxidizer performance test is being done pursuant to 40 CFR 63.363(b)(4)(i).

Please call Mr. Jeffrey Smith at (847) 263-3499 if you have any questions.

Sincerely,

Kevin Wagner
Director EHS

cc: Steve Ortiz, Santa Teresa Facility General Manager

AI/Al/co TSY 1/10002131014
STERIS®
RECEIVED

July 7, 2014

SENT VIA FEDERAL EXPRESS

JUL - 8-2014

Air/Toxics & Inspection
Coordination Branch
6EN-A

Tony Walker
Section Manager
Texas Commission on Environmental Quality
Region 4
2309 Gravel Dr.
Fort Worth, TX 76118

Re: Submission of Summary Report pursuant to 40 CFR Part 63.10(e)(3) and 40 CFR 63.366(a)(3)

STERIS Corporation operates STERIS Isomedix Services, Inc. located at 1175 Isuzu Parkway in Grand Prairie, TX. The facility is required to comply with Subpart O of 40 CFR Part 63, and semi-annual reporting is required pursuant to 40 CFR Part 63.10(e)(3) and 40 CFR 63.366(a)(3).

The facility uses ethylene oxide to sterilize medical products and other materials, and the process consists of three major elements: preconditioning, sterilization, and aeration. All of these elements are part of a continuum necessary to effectively complete the sterilization process. There have been no changes in the CMS, processes or controls since the last reporting period.

Attached, please find the summary report for the period of January 1, 2014 thru June 30, 2014. There were no deviations, nor monitoring equipment changes, that occurred during this period. If you have any questions or need any additional information, feel free to call Scott Cross at (972) 602-9720 or Hayden Schoen at (847) 367-5039.

Sincerely,



Bruce Dewart
Vice President of Operations
STERIS Corporation Isomedix Services

cc: Michelle Kelly
U.S. EPA Region 6
1445 Ross Avenue
Dallas, TX 75202

Hayden Schoen, STERIS Corporation
Scott Cross, STERIS Isomedix Services, Inc.

Attachment

SUMMARY REPORT
DEVIATIONS AND CONTINUOUS PARAMETER MONITORING SYSTEM PERFORMANCE

Company name: STERIS Isomedix Services, Inc.
Address: 1175 Isuzu Parkway
Grand Prairie, TX 75050
HAP monitored at affected source: Ethylene oxide
Parameter monitored: Liquor level in Scrubber Tanks
1L, 1U, 2L, 2U, 3L, 3U, 4L, 4U, 5L, 5U
6L, 6U, 7L, 7U, 8L, 8U, 9L, 9U, 10L, 10U
Reporting period beginning date: January 1, 2014
Reporting period ending date: June 30, 2014
Process unit description: Ethylene oxide from each sterilizer is converted to ethylene glycol by acidic hydrolysis in stage one (L-lower) followed by stage two (U-upper).
Parameter limit: Maximum of 43 inches liquor in scrubber tank
Monitor manufacturer: Not Applicable
Monitor model number: Not Applicable
Date of latest CPMS certification: August 18, 2011
Total operating time of source (hours): 4,344

CPMS Deviations Summary	
1. Minutes of deviations in reporting period due to:	
a. Operating limit for parameter limit not met (minutes):	0
b. Startup/shutdown (minutes):	0
c. Control equipment problems (minutes):	0
d. Process problems (minutes):	0
e. Other known causes (minutes):	0
f. Unknown causes (minutes):	0
2. Total deviation duration (hours):	0
3. Total percentage downtime:	0.00%

CPMS Performance Summary	
1. Minutes of downtime in reporting period due to:	
a. Monitor equipment malfunctions (minutes):	0
b. Non-monitor equipment malfunctions (minutes):	0
c. Quality assurance calibration (minutes):	0
d. Other known causes (minutes):	0
e. Unknown causes (minutes):	0
2. Total CPMS downtime (hours):	0
3. Total percentage downtime:	0.00%

No exceedences of the limited parameter occurred during this reporting period.
The CPMS was not inoperative, out of control, repaired, or adjusted during this period.
I certify that the information contained in this report is true, accurate and complete.


Bruce Dewart
Vice President, Operations

07/05/14
Date